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National Institute for Health Research

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Abstract

Clinical effectiveness and cost-effectiveness of body psychotherapy in the treatment of negative symptoms of schizophrenia: a multicentre randomised controlled trial

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Background: The negative symptoms of schizophrenia significantly impact on quality of life and social functioning, and current treatment options are limited. In this study the clinical effectiveness and cost-effectiveness of group body psychotherapy as a treatment for negative symptoms were compared with an active control.

Design: A parallel-arm, multisite randomised controlled trial. Randomisation was conducted independently of the research team, using a 1 : 1 computer-generated sequence. Assessors and statisticians were blinded to treatment allocation. Analysis was conducted following the intention-to-treat principle. In the cost-effectiveness analysis, a health and social care perspective was adopted.

Participants: Eligibility criteria: age 18–65 years; diagnosis of schizophrenia with symptoms present at > 6 months; score of ≥ 18 on Positive and Negative Syndrome Scale (PANSS) negative symptoms subscale; no change in medication type in past 6 weeks; willingness to participate; ability to give informed consent; and community outpatient. Exclusion criteria: inability to participate in the groups and insufficient command of English.

Settings: Participants were recruited from NHS mental health community services in five different Trusts. All groups took place in local community spaces.

Interventions: Control intervention: a 10-week, 90-minute, 20-session group beginners' Pilates class, run by a qualified Pilates instructor. Treatment intervention: a 10-week, 90-minute, 20-session manualised group body psychotherapy group, run by a qualified dance movement psychotherapist.

Outcomes: The primary outcome was the PANSS negative symptoms subscale score at end of treatment. Secondary outcomes included measures of psychopathology, functional, social, service use and treatment satisfaction outcomes, both at treatment end and at 6-month follow-up.

Results: A total of 275 participants were randomised (140 body psychotherapy group, 135 Pilates group). At the end of treatment, 264 participants were assessed (137 body psychotherapy group, 127 Pilates group). The adjusted difference in means of the PANSS negative subscale at the end of treatment was 0.03 [95% confidence interval (CI) –1.11 to 1.17], showing no advantage of the intervention. In the secondary outcomes, the mean difference in the Clinical Assessment Interview for negative symptoms expression subscale at the end of treatment was 0.62 (95% CI –1.23 to 0.00), and in extrapyramidal movement disorder symptoms –0.65 (95% CI –1.13 to –0.16) at the end of treatment and –0.58 (95% CI –1.07 to –0.09) at 6 months' follow-up, showing a small significant advantage of body psychotherapy. No serious adverse events related to the interventions were reported. The total costs of the intervention were comparable with the control, with no clear evidence of cost-effectiveness for either condition.

Limitations: Owing to the absence of a treatment-as-usual arm, it is difficult to determine whether or not both arms are an improvement over routine care.

Conclusions: In comparison with an active control, group body psychotherapy does not have a clinically relevant beneficial effect in the treatment of patients with negative symptoms of schizophrenia. These findings conflict with the review that led to the current National Institute for Health and Care Excellence guidelines suggesting that arts therapies may be an effective treatment for negative symptoms.

Future work: Determining whether or not this lack of effectiveness extends to all types of art therapies would be informative.

Trial registration: Current Controlled Trials ISRCTN842165587.

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List of abbreviations

ADMP	Association of Dance Movement Psychotherapy
BPT	body psychotherapy
CACE	complier-average causal effect
CAINS	Clinical Assessment Interview for Negative Symptoms
CEAC	cost-effectiveness acceptability curve
CEP	cost-effectiveness plane
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	case report file
CSQ	Client Satisfaction Questionnaire
CSRI	Client Service Receipt Inventory
CTU	Clinical Trials Unit
DMEC	Data Monitoring and Ethics Committee
EPS	extrapyramidal side effect
EQ-5D	European Quality of Life-5 Dimensions
EQ-5D-5L	European Quality of Life-5 Dimensions, five-level version
GP	general practitioner
ICC	intraclass correlation coefficient
ICD-10	*International Classification of Diseases*, Tenth Edition
ICER	incremental cost-effectiveness ratio
IQR	interquartile range
ISRCTN	International Standard Randomised Controlled Trial Number
MANSA	Manchester Short Assessment of Quality of Life
MATISSE	Multicentre evaluation of Art Therapy In Schizophrenia: Systematic Evaluation
NICE	National Institute for Health and Care Excellence
PANSS	Positive and Negative Syndrome Scale
PCTU	Pragmatic Clinical Trials Unit
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
REPS	Register of Exercise Professionals
SANS	Scale to Assess Negative Symptoms
SAS	Simpson–Angus Scale
SD	standard deviation
SNS	Social Network Scale
TAS	Toronto Alexithymia Scale
TSC	Trial Steering Committee
TUS	Time Use Survey

Plain English summary

Symptoms of schizophrenia, such as reduced emotions and lack of drive, can reduce a person's quality of life. At present, there are few treatment options that have been found to help. Arts therapies (which involve different, more creative ways to help people communicate than just talking) may be helpful, but more evidence is needed.

One form of art therapy is body psychotherapy, which uses movement and the body as a form of treatment. In a recent small study, body psychotherapy was found to reduce symptoms, but it is not clear if it is the group activity or the therapy itself that caused the improvement, or if the improvement would still occur if the treatment was conducted at different sites by different therapists.

In this study, 275 people were randomised to take part in a 20-session body psychotherapy group or a 20-session Pilates class. Symptoms, the cost of health services used and measurements of well-being were taken before the first group session, after the last session and then again 6 months later. The measurements from the participants who were offered the body psychotherapy group were then compared with those who were offered the Pilates class.

In both groups only very small improvements in symptoms were found, which means that the body psychotherapy group did not improve symptoms more than Pilates. These findings appear to contradict the current guidelines, which suggest that art therapies may be helpful in addressing a lack of drive and reduced emotions.

Scientific summary

Background

The negative symptoms of schizophrenia refer to expressive deficits, such as impoverished speech and blunted affect, and experiential/pleasure deficits, such as anhedonia, avolition and asociality. These negative symptoms have been found to be largely resistant to antipsychotic medication and conventional psychotherapeutic interventions, and significantly impact on quality of life and social functioning. There is some evidence to suggest that arts therapies could be effective in the treatment of these symptoms; however, the current data are limited and full-scale trials are required.

In a review by the National Institute for Health and Care Excellence (NICE), arts therapies – which is a label covering all creative therapies, such as music therapy, art therapy, body psychotherapy (BPT), dance movement psychotherapy and drama therapy – were the only type of intervention found to demonstrate consistent efficacy in the amelioration of negative symptoms. However, given that the findings were based on only six small-scale studies, the recommendations for further research recognised the need for larger trials. In addition, it was recommended that trials include an active control group in order to control for any non-specific effects of taking part in group activities.

The aim of this trial is to assess the clinical effectiveness and cost-effectiveness of a manualised form of group BPT that was designed to treat the negative symptoms of schizophrenia in outpatients, comparing outcomes with those from outpatients attending Pilates classes. Pilates is a type of structured physical fitness programme involving stretching and controlled movement, which will control for the effects of therapist attention and group-structured physical activity. In comparing BPT with a physically active control, the aim of the trial was to evaluate the specific components of BPT, which includes the focus on body experience at a cognitive and emotional level, the facilitation of emotional group interactions and the link between movement and emotion.

Objectives

The objectives were to:

1. test the effectiveness of a manualised group BPT intervention in reducing negative symptoms of schizophrenia compared with an active control
2. test the effectiveness of a manualised group BPT intervention in general psychopathology, quality of life, daily activities, objective social situation and treatment satisfaction in participants who were experiencing negative symptoms of schizophrenia compared with an active control
3. test whether or not any effects on primary and secondary outcomes are maintained at 6 months' follow-up
4. assess the cost impact, cost-effectiveness and cost–utility of BPT.

Method

The study was a two-arm, parallel-group, multisite randomised controlled trial (RCT). Patients with schizophrenia [*International Classification of Diseases*, Tenth Edition (ICD-10) codes F20.0–F20.9] experiencing at least moderate levels of negative symptoms [score of ≥ 18 on the Positive And Negative Syndrome Scale (PANSS) negative subscale] were randomised into a 20-session (10-week) BPT group, or a 20-session (10-week) Pilates class. Randomisation was conducted by a statistician from the Clinical Trials Unit through a computer-generated sequence. Participants were randomly allocated, with equal probability, to the intervention or control group, stratified by study centre, in batches using randomly permuted blocks of 4 and 6, starting each batch at the start of a new block in order to preserve balance. Assessors and statisticians were blinded to treatment allocation until the analysis plan was signed off. Analysis was conducted following intention-to-treat principles.

Participants

Participants were recruited from the UK NHS mental health community services in five different Trusts. The eligibility criteria included ages 18–65 years; ICD-10 diagnosis of schizophrenia, with symptoms present for at least 6 months; score of ≥ 18 on PANSS negative symptoms subscale; no change in medication type in the past 6 weeks; willingness to participate; ability to give informed consent; and community outpatient. The exclusion criteria included inability to participate in the groups because of physical disability or condition and insufficient command of English. All groups took place in local community spaces.

Procedures

Potentially eligible participants were approached by their clinicians for their consent to be contacted by a researcher. If they agreed, the researcher arranged a meeting during which a detailed explanation of the study was provided, and, presuming that they were interested in taking part, informed consent was obtained. An eligibility assessment using the PANSS scale was then conducted to ascertain whether or not they had a rating of at least 18 on the negative symptoms subscale, in accordance with the inclusion criterion. Once approximately 16 eligible participants at each site were recruited, a full baseline assessment – which included a second PANSS assessment – was undertaken 1 month prior to the group start date. The assessments were typically conducted in the participants' homes or at their local community mental health team base.

On completion of the groups, the researchers contacted the participants again for the end-of-treatment assessment, which included all of the structured interviews and questionnaires obtained in the baseline assessment, in addition to the Client Satisfaction Questionnaire (CSQ) which was used to measure the participants' satisfaction with treatment. Six months after intervention completion, patients were contacted a final time to arrange the follow-up assessment, which, again, included all of the interviews and questionnaires of the baseline assessment.

The treatment under investigation was BPT, as outlined in an updated version of the manual used in the 2006 exploratory trial. Both BPT and the Pilates groups were delivered twice per week on non-consecutive days for 10 weeks, with each session lasting 90 minutes. A maximum of 10 participants were assigned to each group or class. To limit the impact of any one body psychotherapist or Pilates instructor on outcomes, each one was permitted to run a maximum of two groups.

The BPT group was facilitated by an Association of Dance Movement Psychotherapy (ADMP) accredited therapist, who had attended an additional 2-day training course in delivering the intervention in its manualised form. In each group, the therapist was supported by a volunteer as cofacilitator. Each therapist received a minimum of three 90-minute supervision sessions held by a senior therapist for each group, either in person or via a videoconference.

Each of the 20 sessions comprised five discrete sections. The first was the opening circle, which is used to describe feelings and energy levels; the second was a warm-up section, for which the participants stand in a circle and warm up using different body parts and movements; the third was a structured task section with exercises, such as mirroring each other's movements and creating body image sculpture in partners; the fourth consisted of creative movements, with exercises such as creating group sculptures and reflecting on perceptions and emotions; and finally, the fifth was a closing circle, which was used to reflect on the group experience and to refocus on the self with body-orientated exercises.

The Pilates classes were held in the same venues as the BPT groups. All classes were facilitated by a Register of Exercise Professionals (REPS) level 3-qualified Pilates instructor, and assisted by a cofacilitator. Prior to the classes starting, a brief training session was arranged between the instructor and an experienced clinician.

Outcomes

The primary outcome was the PANSS negative symptoms subscale score, which was assessed at the end of treatment. Secondary outcomes included the PANSS negative subscale score at 6 months post treatment, in addition to general psychopathology and positive symptoms (PANSS), subjective quality of life (Manchester Short Assessment of Quality of Life; MANSA), level of activity (items from the Time Use Survey; TUS), objective social situation (SIX), extrapyramidal symptoms resulting from antipsychotic medication (Simpson–Angus Scale; SAS), emotional experience and expression (Clinical Assessment Interview for Negative Symptoms; CAINS), depression (Calgary Depression Scale) and social contacts (Social Network Scale; SNS), measured both at end of treatment and at 6 months' follow-up. Satisfaction of treatment was measured at the end of the treatment phase (Client Satisfaction Questionnaire; CSQ). In addition, cost impact, cost-effectiveness and cost–utility were assessed using the European Quality of Life-5 Dimensions (EQ-5D) and the Client Service Receipt Inventory (CSRI).

Statistical methods

A 20% reduction in the PANSS score was used as an indicator of clinically significant improvement, which would be a difference of approximately 3 points, given the eligibility criteria. To detect this difference with a standard deviation (SD) of 5, with 90% power for 5% significance, 58 patients were required in each arm. To allow for clustering by group, an intraclass correlation coefficient (ICC) for treatment group of 0.1, and seven patients per group with analysable data at the end of treatment, gives an inflation factor of 1.6, meaning that 93 participants in each arm were required. At 6 months we anticipated a loss to follow-up of 31%, so recruiting 256 participants would leave 88 per arm at 6 months, and 91% power to detect a difference of 3 points at this time point.

The primary analysis was of available cases of the PANSS negative subscale at end of treatment, following intention-to-treat principles. We used a mixed-effects model, fitted by restricted maximum likelihood with fixed effects for the intervention, baseline PANSS negative subscale scores, and centre (because it was used to stratify the randomisation), and random effects for therapy groups to allow for clustering by group. Secondary outcomes were analysed using the same approach. To evaluate the impact of missing data, multiple imputation of the data set was performed and the analysis was replicated. A simple complier-average causal effect analysis (CACE) was completed. In this analysis, compliance was defined as attending at least five sessions, following the results of a recent study that evaluated the effectiveness of BPT for chronic depression. Planned subgroup analyses examining whether or not there were differences in response between those with higher negative symptoms at baseline and a longer duration of illness were also conducted. All analyses were completed using Stata version 12 (StataCorp LP, College Station, TX, USA).

Results

In total, 275 participants were randomised: 140 to the BPT group and 135 to the Pilates group. Each group comprised between 7 and 10 participants. Attendance was relatively high in both groups; however, participants attended significantly more sessions in the BPT arm than in Pilates group [BPT median = 11, interquartile range (IQR) = 5–17; Pilates median = 8, IQR = 1–15; $p = 0.01$]. In the BPT arm, 106 participants (75.7%) attended at least 5 of the 20 sessions, thus fulfilling the minimum attendance threshold required to be defined as a treatment complier in the CACE analysis.

In the primary outcome, no significant difference between the experimental and control condition was detected [adjusted difference in the means = 0.03, 95% confidence interval (CI) –1.11 to 1.17; $p = 0.959$, model-based ICC = 0.099 after controlling for baseline scores, study centre and therapy group]. In the secondary outcomes at the end of treatment, a significant mean difference reduction in the SAS (–0.65, 95% CI –1.13 to –0.16; $p = 0.009$, ICC < 0.001) and the CAINS expression subscale (–0.62, 95% CI –1.23 to 0.00; $p = 0.049$, ICC = 0.022) was detected in favour of the BPT arm in comparison with the Pilates group at the end of treatment. No other significant differences were found in the secondary outcomes at this stage. At the 6-month follow-up, a significant mean difference in the SAS was detected (–0.50, 95% CI –0.97 to –0.07; $p = 0.028$, ICC < 0.001); however, no other differences were detected.

In the CACE analysis, a significant difference was found in the SAS at end of treatment (–0.82, 95% CI –1.51 to –0.12); however, no other differences were detected, including in the primary outcome of negative symptoms. No significant differences in negative symptoms were detected in the subgroup analysis, which compared those with high and low negative symptoms, and long and short duration of illness. There were no serious adverse events related to the intervention.

The total mean costs per participant in the BPT over the whole follow-up period were £2297 (SD = £2835) in comparison with £2442 (SD = £3278) for Pilates. After adjusting for baseline, the total costs were slightly lower for BPT; however, the difference was non-significant (£25; bootstrapped 95% CI –£671 to £721). No significant differences were detected in the sensitivity analysis, for which the costs of Pilates were changed to zero (–£55, 95% CI –£630 to £706). No significant differences were detected in quality-adjusted life-years (QALYs) between BPT and Pilates (adjusted difference in means = 0.01; 95% CI –0.02 to 0.04). At £20,000 per QALY, it was found that there is approximately a 65% likelihood that BPT is a more cost-effective option than Pilates.

Conclusions

No significant differences between BPT and Pilates were detected in the PANSS negative symptoms subscale, both at the end of treatment and 6 months later. A statistically significant improvement in the BPT group in comparison with the Pilates group was detected in the CAINS expression subscale at the end of treatment, and, in movement disorder symptoms, both at end of treatment and 6 months later. However, the small effect sizes mean these are unlikely to reflect relevant clinical benefits. There was no significant difference on any other outcome. Given the results and the high statistical power, these findings support the conclusion that BPT is not an effective treatment for patients with negative symptoms of schizophrenia compared with Pilates as an active control.

Implications for health care

In comparison with an active control, group BPT does not have a clinically relevant beneficial effect in the treatment of patients with negative symptoms of schizophrenia. These results are consistent with an earlier RCT [Multicenter evaluation of Art Therapy in Schizophrenia: Systematic Evaluation (MATISSE)] evaluating the effectiveness of art therapy as a treatment for schizophrenia and, together, contradict current NICE guidelines, which suggest that arts therapies are an effective treatment for negative symptoms.

Trial registration

This trial is registered as ISRCTN842165587.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Background

Schizophrenia and negative symptoms

Schizophrenia is a severely disabling mental health disorder that affects approximately 0.7% of the population.[1] The main symptoms are commonly characterised into 'positive' symptoms, which include hallucinations, disordered thinking and delusions, and 'negative' symptoms, which refer to deficits in emotional experience and expression. Specific symptoms relating to emotional expression include blunted affect and alogia (impoverished speech), whereas deficits in emotional experience can include asociality, anhedonia (inability to anticipate or experience pleasure) and amotivation.[2]

Negative symptoms have been found to be highly detrimental to social outcomes, quality of life and functioning,[3,4] and so are important targets for treatment. However, despite developments in both antipsychotic medication and psychological treatments, the effectiveness of most treatments on negative symptoms has been found to be limited.[5] This being the case, the negative symptoms are currently recognised as an unmet therapeutic need in a large proportion of cases.[5]

Schizophrenia and arts therapies

'Arts therapies' is an umbrella term for a range of different therapies, which include music therapy, art therapy, body psychotherapy (BPT), dance movement psychotherapy and drama therapy. Common to all of them is that they have a central non-verbal component, with the focus on utilising creative activities to achieve psychological change. In a review on treatment strategies in schizophrenia by the National Institute for Health and Care Excellence (NICE), arts therapies were found to be the only type of treatment to demonstrate clear, consistent improvement in negative symptoms;[6,7] however, the sample size for the meta-analysis was small (six trials, $n = 382$), leading to the suggestion that the evidence base should be increased with more large-scale trials of arts therapies. Furthermore, none of the studies compared the intervention with an active control, so it remains unclear whether it is the specific effects of the psychotherapeutic component of arts therapies or the non-specific effects of regular group activity that are driving the changes. Finally, no studies evaluating evidence on the cost-effectiveness of such interventions were identified. Consequently, the research recommendations suggested that further trials should be conducted to test the clinical effectiveness and cost-effectiveness of arts therapies for patients with schizophrenia, that such trials should be sufficiently powered and that they should use an active control.

Since the recommendations were published, a full-scale, multicentre randomised controlled trial (RCT) evaluating the effectiveness of art therapy has been completed [Multicenter evaluation of Art Therapy in Schizophrenia: Systematic Evaluation (MATISSE)].[8] In this study, no significant improvements in either negative symptoms or any of the secondary outcomes were found in the art therapy group, relative to either the active control group or standard care. The MATISSE trial[8] was designed as a pragmatic trial with the aim of testing the impact of group art therapy delivered in current clinical practice, meaning that one specific model of therapy was not evaluated. Consequently, the type of treatment provided was not consistently applied, which has been criticised by some art therapists, who have suggested that what was evaluated is not what is routinely delivered in the UK.[9,10] In response to this critique, the MATISSE study team have since published a more comprehensive description of the therapy delivered,[11] which contends that such a method of implementation is consistent with the principles of pragmatic trials. Regardless, new trials of arts therapies that implement a standardised therapy, recognised as appropriate for the patient group beforehand, would be a significant advance in the evidence base.

Following the MATISSE trial,[8] a second important issue is that it is not currently clear whether any lack of effectiveness in the treatment of negative symptoms is specific to the art therapy that was delivered in this context or endemic to all 'arts therapies' as a whole. In recognition of this, the MATISSE[8] trial research recommendations suggest that 'Data from exploratory trials of other creative therapies, including music therapy and body movement therapy, have shown promising results and randomised trials examining the clinical effectiveness and cost-effectiveness of offering these interventions to people with schizophrenia should be conducted' (p. xii).[8] Therefore, research on other arts therapies modalities might help to assess whether the lack of efficacy of art therapy on negative symptoms is particular to this type of psychotherapy or is indicative of arts therapies as a whole.

Body psychotherapy and schizophrenia

Of the six studies included in the NICE review,[6] three studies[12–14] evaluated the effectiveness of music therapy, two studies[15,16] evaluated the effectiveness of art therapy and one study[17] evaluated the effectiveness of body-orientated psychotherapy. The BPT trial was an exploratory RCT, which tested a manualised form of the intervention in outpatients with persistent negative symptoms of schizophrenia. Compared with a control group receiving supportive counselling, patients in the experimental group showed a significant improvement in negative symptoms. The effect size was large, and maintained at 4 months' follow-up. The major limitations of the study were that it was a small exploratory trial, based at one site and with only one body psychotherapist, and that the control condition was supportive counselling, which turned out to be unattractive to patients. In addition, the non-specific effects of physical activity could not be controlled for and the study was insufficient in size to evaluate cost-effectiveness. Following these findings, an open uncontrolled trial of manualised BPT[18] was conducted by the same authors, but different therapists, which yielded similar results; however, no other rigorous trials on BPT or a similar method have been identified in a recent Cochrane review update.[19]

Regarding earlier trials on BPT and schizophrenia, which are not included in the NICE review, the earliest trial was published in 1965[20] and found significant improvements of affective contact and general functioning. Since then, further investigations of body-orientated psychotherapy have suggested some improvements in a range of outcomes, including some indicators of negative symptoms.[21–23] However, all of these studies, which were exclusively conducted before 1980, have serious methodological shortcomings, such as small sample sizes, vaguely defined outcome criteria, no systematic assessment of psychopathology, no recording of medication, no intention-to-treat analysis and a poorly defined description of the intervention under investigation. Overall, there is current and historic evidence to suggest that BPT might be effective in the treatment of schizophrenia; however, further evidence from rigorous, full-scale trials is required.

Theoretical basis for body psychotherapy as a treatment for schizophrenia

Body-orientated psychotherapies have a long tradition in psychiatry and have existed in many different forms, which can lead the field to appear somewhat heterogeneous. In a review of the field,[24] Röhricht identified the three main historical roots of BPT as neo-Reichian psychotherapies, concentrative movement therapy and dance movement psychotherapies, but suggested that, in practice, a substantial degree of overlap exists between the different schools of thought. In the review it was proposed that the immediacy of bodily experience may be an important tool in reality testing and developing a sense of inter-relational embodiment, and so therefore may offer unique benefits in working with those with psychosis.

Three different models of mechanism have been proposed in support of the hypothesis that BPT may be an effective treatment for schizophrenia and negative symptoms. Regarding the first,[25] one of the core features of negative symptoms relates specifically to diminished emotional expression. Consequently, patients can often experience significant barriers when engaging in conventional psychotherapies in which verbalising emotions and cognitions may be a core component of the treatment. BPT offers an alternative, non-verbal model of facilitating emotional interactions, which some patients might find preferable or more accessible.

The second model of mechanism relates to the link between movement and emotion. Patients with schizophrenia often experience significant deficits in emotional experience, and can display a range of motor abnormalities.[25,26] Central to BPT is the link between movement and emotional experience, encouraging the patient to focus on the immediacy of experiences, which may result in, or from, movement. In doing so, this further opens greater opportunities for reality testing, and can reinforce the idea that the body can be a source of creativity and pleasure. This may be significant when working with patients who report significant deficits in anticipating pleasure.[27] This emotional learning can be further enhanced by the group experience, when patients can observe and imitate expressive movements in other patients.

The third model of mechanism is related to how BPT can potentially enhance body and self-experience. Patients with schizophrenia can frequently have misperceptions regarding their body, and altered body experience in the form of disturbed body perception and body image.[28,29] As such, a therapeutic method that places particular emphasis on the patients' perceptions and experiences of their body, and its movements may be an effective way of addressing these symptoms.

Features of the body psychotherapy treatment

Presuming that the therapy is effective, there are a number of potential advantages, inherent in BPT, which may make it an attractive option to health providers. First, as a group-based method, BPT is relatively inexpensive. In addition, it can be administered by existing clinicians, employed by the UK NHS, after minimal additional training, and the groups can be held in standard therapy spaces. Second, BPT can be flexibly combined with other treatment methods, including all pharmacological interventions. Third, given that the focus of treatment is non-verbal in nature, centring instead on body movement and creativity, the treatment may be more accessible to patients who present with negative symptoms, such as alogia. Lastly, because BPT is so distinct from conventional treatment methods, it may appeal to patients who struggle to engage in other forms of treatment. The latter point is underlined by findings of a qualitative evaluation of the exploratory trial,[18] in which patients fed back positively about both its focus and methods.

Effects of physical activity in schizophrenia

As previously highlighted, one of the limitations in the earlier exploratory trial[17] was that the control condition was group-supportive counselling, which meant that the non-specific effects of physical activity could not be controlled for. In a recent Cochrane review,[30] there is some evidence to suggest that exercise may be at least partially effective in the treatment of negative symptoms, whereas others[31] have examined possible neurological effects of increased physical activity in schizophrenia. This being the case, at present it is not clear whether or not the psychotherapeutic content of the sessions provide any additional benefit over and above what may be achieved from regular activity.

In order to examine the specific effects of this particular treatment, BPT was compared with a structured physically active control group, namely a beginner's Pilates class. Pilates was chosen as the active control condition as it can be delivered in a structured format by a trained instructor, does not foster group interaction and does not include elements that are broadly equivalent to mindfulness like other low-intensity activities, such as yoga or t'ai chi. By comparing BPT with an active control, this investigation will allow for the evaluation of the specific effects of the therapy. In the event that no significant difference between the treatment conditions is found, disentangling whether they are both equally effective, as opposed to neither being effective, may be impossible to achieve in the absence of a treatment-as-usual arm. However, in a small trial[32] examining the effectiveness of yoga therapy, in comparison with an active control condition, a significant improvement in negative symptoms was found, which suggests the approach adopted in this trial is a feasible one.

Aims and objectives

Following the recommendations of NICE,[6] we conducted a multisite, RCT to compare the effectiveness of BPT with a physically active control condition, namely Pilates. In controlling for the effects of therapist attention and regular structured physical activity, the specific components of the treatment under investigation were the focus on body experience at a cognitive and emotional level, the facilitation of emotional group interactions, and the link between movement and emotion. The Pilates group controlled for the effect of therapist attention and structured physical activity as alternative explanations of the effect discovered in the exploratory trial.

The aims of this trial were to:

1. test the effectiveness of a manualised group BPT intervention in reducing negative symptoms of schizophrenia compared with an active control
2. test the effectiveness of a manualised group BPT intervention in general psychopathology, quality of life, daily activities, objective social situation and treatment satisfaction in patients experiencing negative symptoms of schizophrenia compared with an active control
3. test whether or not any effects on primary and secondary outcomes are maintained at 6 months' follow-up
4. assess the cost impact, cost-effectiveness and cost–utility of BPT.

Chapter 2 Methods

Design

The study is an assessor-blinded, parallel-arm RCT. A detailed study design description is available in the published protocol.[13] Prior to recruitment, the study was registered through the International Standard Randomised Controlled Trial Number (ISRCTN) system (ISRCTN84216587).

Amendments to the protocol

Through the implementation of the project, five amendments were made, all approved by the Research Ethics Committee (REC) and the study sponsors prior to implementation. The changes included are listed below.

Amendment 1

On the advice of the Trial Steering Committee (TSC) an additional inclusion criterion was added, specifying that the type of antipsychotic medication prescribed to participants should not change for at least 6 weeks prior to baseline assessment, although a change in dosage is acceptable. In addition, the Calgary Depression Scale[33] was added to the case report file (CRF) battery, again on the suggestion of the TSC. During the set-up phase, the complexities of arranging the logistics for each session were becoming increasingly apparent, so the protocol was changed to include a volunteer cofacilitator to aid both the therapists and instructors for each group. Last, a minor amendment was made to the consent form, including the additional clause 'I agree that if I withdraw, or am withdrawn from the study for any reason, then the researcher can continue to use the information I have already given them' at the request of one of the NHS research sites.

Amendment 2

The Social Network Scale (SNS)[34] was added to the CRF in an attempt to record an objective measure of the social network of participants.

Amendment 3

The Toronto Alexithymia Scale (TAS)[35] and the Scale to Assess Negative Symptoms (SANS)[36] Anhedonia subscale item were replaced by the Clinical Assessment Interview for Negative Symptoms (CAINS)[37] in the CRF battery, a new instrument that follows a much closer conception of what we currently understand negative symptoms to be.[2]

Amendment 4

The filming of the groups was extended to also include the physical activities arm of the study and the CAINS interviews[37] to enable inter-rater reliability assessments. A minor revision of the participant information sheet and consent form was conducted in order to reflect these changes.

Amendment 5

During data collection, it was becoming apparent that a number of participants struggled to remember historical information regarding the number and type of hospitalisations in addition to their medication details. To rectify this issue, a final amendment to the protocol was made in order to allow research assistants to check medical records to accurately source this data. A minor amendment to the consent form was made, adding a clause through which participants could either consent or refuse permission to access medical records. For participants who had already consented to take part in the trial prior to this amendment being approved, an addendum to the original form was attached and additional consent was sought in their next assessment.

Eligibility criteria

Inclusion criteria

- Aged between 18 and 65 years.
- Diagnosis of schizophrenia according to the *International Classification of Diseases*, Tenth Edition (ICD-10).
- Symptoms of schizophrenia present for at least 6 months.
- Scores of ≥ 18 on the negative symptoms subscale of the Positive and Negative Syndrome Scale (PANSS).[38]
- No change in the type of antipsychotic medication prescribed within the previous 6 weeks (although the dosage may change).
- A willingness to participate in a BPT or Pilates group.
- An ability to give written informed consent.

Exclusion criteria

- A severe physical disability or condition that prevents patients from participating in light activity.
- An insufficient command of English in relation to the nature of the group intervention and assessment interviews.

Outcome measures

The primary outcome criterion used to test for the effectiveness of BPT was the change in negative symptoms measured by the PANSS,[38] completed at the end-of-treatment stage. The PANSS is a 30-item semistructured interview that is designed to provide an overall measure of the symptoms of schizophrenia. In the original format, 16 of the items relate to general psychopathology, seven items relate to positive symptoms of schizophrenia (such as hallucinations and delusions) and seven items relate to negative symptoms. Each item is rated on a scale of 1–7, covering both the severity and frequency of the symptoms assessed, resulting in a range of 7–49 for positive and negative symptoms and 16–112 for general symptoms. The subscales of the PANSS have been found to have good internal consistency,[39] good inter-rater reliability and concurrent validity,[40] and the scale is recognised to be one of the established symptom scales in schizophrenia research.[41]

As a exploratory outcome, the alternative Marder factor solution of the PANSS was also adopted, given concerns that the original format includes some items that have more recently been found to relate to cognitive, rather than negative, symptoms.[42,43] In this alternative configuration, the 'abstract thinking' and 'stereotypical thinking' items are dropped, and replaced with the 'active social withdrawal' and 'motor retardation' items. In addition to the Marder-configured subscale, the standard positive and general PANSS subscale scores were also used as secondary outcomes to measure other aspects of psychopathology.

Other secondary outcomes include the Manchester Short Assessment of Quality of Life (MANSA),[44] which measures aspects of both subjective and objective aspects of quality of life; the participants' current objective social situation measured on the SIX;[45] extrapyramidal symptoms measured on the Simpson–Angus Scale (SAS);[46] depression measured on the Calgary Depression Scale;[33] an alternative measure of negative symptoms that evaluates expressive and experiential deficits, CAINS;[37] four items taken from the Time Use Survey (TUS) to get a measure of the types of activities in which participants take part; an adaptation of the Social Network Scale (SNS)[34] to measure the frequency of their social contacts over the past week; and, finally, participant satisfaction with the group into which they are randomised using the Client Satisfaction Questionnaire (CSQ).[47] In addition, the EQ-5D-5L (European Quality of Life-5 Dimensions, five-level version)[48] and the Client Service Receipt Inventory (CSRI) were completed in order to allow for an analysis of cost-effectiveness, cost–utility and cost impact of the intervention.[49] All of the

scales were completed at all three assessment stages (baseline, end of treatment and 6 months post treatment) other than the CSQ, which was completed only at the end-of-treatment stage. For all scales, interviewees were asked to report their symptoms and experiences over the previous week, apart from the TUS, which collects information over the previous month; the CSQ, which aimed to assess the satisfaction of the groups over the whole 10 weeks; and the visual analogue scale of the ED-5Q-5L, which asks participants how they would rate the quality of their health on the day on the interview. At the baseline assessment, the CSRI was used to assess the previous 3 months of service use, whereas at the end-of-treatment and 6-month follow-up stages only the previous month was assessed. All outcome measures were scored as part of a structured interview with the researcher.

The MANSA[44] is a 16-item questionnaire that is designed to measure quality of life. The scale consists of 16 items: 12 covering subjective quality of life and four covering objective indicators. The 12 subjective items are measured on a 1- to 7-point Likert scale, covering satisfaction with employment, finances, recreational activities, friendships, safety, housing, health, sex life, family and overall life satisfaction. The four objective items are 'yes or no' questions and cover whether or not the participant has been a victim of a crime, has been accused of crime, has anyone he/she considers to be a close friend or has seen a friend in the past 7 days. The summary score from the MANSA is calculated by taking a mean of the 12 subjective items, with a high score indicating a greater satisfaction with quality of life.

The SIX[45] is an instrument designed to measure the individual's objective social situation. The scale consists of four questions: employment (whether or not he/she is employed, unemployed or taking part in voluntary, protected work); housing (whether or not he/she has independent accommodation, sheltered/supported housing or is homeless); the participant's living situation (lives alone or with partner/family); and friendship (has he/she met a friend in the past week). The responses of each item are added together, resulting in a score ranging from 0 to 6, with a high score indicating a more positive social situation.

The CAINS[37] is a recently devised assessment of negative symptoms, comprising 13 items, each rated on a scale of 0–4. The first nine items relate to experiential/pleasure deficits, whereas the last four items relate to expressive deficits of the disorder. For each subscale a mean score of the responses is calculated, resulting in a range of 0–4 for both experiential and expressive deficits. In both cases a higher score represents more severe psychopathology.

The Calgary Depression Scale[33] is an assessment tool that is designed to measure depressive symptoms and is specifically adapted for schizophrenic populations. In order to appropriately differentiate from negative symptoms, which also include anhedonia and amotivation, the scale primarily focuses on the interviewee's low mood, hopelessness, feelings of guilt and perception of self. The scale comprises nine items, rating from 0 (absent) to 3 (severe), giving a total range of 0–27, with a higher score representing a more severe psychopathology.

The size of the participants' social network was measured using a simplified version of the SNS, which was first used in an observational study by Dunn *et al.*[34] looking at the social life of long-stay patients. In this study,[34] the focus was on establishing the size of the social network in which participants typically operated during their day-to-day lives. Participants were required to list all of the people to whom they had spoken in the past week, identify their relationship to that individual and then report on how many days in the past week they had spoken to them. Unlike in the original form of the schedule, participants were not asked to report any additional details regarding the quality of their relationship with individuals.

The SAS[46] is a scale designed to measure movement disorder symptoms that are related to extrapyramidal side effects (EPSs). The scale includes 10 different items, rated from 0 to 4, with a higher score denoting a greater severity of EPS. To rate each item, the assessors were required to observe different aspects of the interviewee's movement or physical appearance, such as his/her gait, severity of any tremor, and whether or not he/she produces excess saliva, and, by conducting simple physical examinations, including checking wrist, elbow and shoulder rigidity. Given that a significant proportion of assessments were conducted in

the participant's home, and by non-medically trained researchers, two items that required medical apparatus, such as a medical table (head dropping and leg pendulousness), in addition to the glabellar tap, were not conducted. Therefore, the adapted summary score produced for the purposes of this study ranged from 0 to 32.

A measure of the number of activities in which participants took part was captured by the TUS. The aim of the questionnaire was to provide a brief summary of the range of activities undertaken by the interviewee over the previous week. The scale included four items: asking the participant whether or not they had (1) eaten out at a café, restaurant, pub or wine bar; (2) been shopping for non-household/essential items; (3) been to any type of place of entertainment, such as a club, bingo hall, cinema, museum or casino, etc.; or (4) been on any outdoor trips, such as going to the park, beach or any other place of natural beauty. Participants reported how many times they had been to each place in the past month, and for the length of time for each time they went there. The items themselves were taken, and adapted, from an interview schedule drafted by the Office for National Statistics to measure time use.[50]

The CSQ[47] is a nine-item self-report questionnaire that assesses how satisfied the interviewee is with the intervention they received. Each item is rated from 1 to 4, with a larger score representing a greater satisfaction with the treatment.

The ED-5Q-5L[48] is a scale that is designed to evaluate self-reported health-related quality of life, and was used as the main outcome measure in the economic analysis. The scale consists of five items, which, together, produce a summary score and a separate visual analogue scale. The item section of the questionnaire asks the interviewee whether or not he/she experiences impairments in health (related to mobility, self-care, conducting activities, pain/discomfort and anxiety/depression). These are rated as '1' (no problems), '2' (slight), '3' (moderate problems), '4' (severe problems) or '5' (unable/extreme), and this gives rise to 3125 distinct health states (from 11111 to 55555). These were weighted by standardised value sets based on UK tariffs[51] to estimate utility, which are anchored by '1' (full health) and '0' (death). The weights attached to each health state are then combined using area-under-the-curve methods to derive the total quality-adjusted life-years (QALYs) that are accrued over the follow-up period.

The visual analogue section of the EQ-5D-5L ranges from 0 to 100, and asks the interviewee to place a cross on a continuous line, which would represent how they would rate their health today, with '0' being 'the worst health you can imagine', and '100' being 'the best health you can imagine'.

The version of the CSRI[49] used in this study aimed to assess the cost of services received and comprised four discrete sections. The first related to whether or not the participant had been in contact with any community health service providers and, if so, how many times and, on average, how long for. The second part aimed to measure whether or not the participant had been in receipt of any specialised services, related to physical or mental health, and the setting in which they were seen (i.e. inpatient stay, outpatient hospital appointment or community services). The third section related to the type and amount of mental health medication that he/she was prescribed. The fourth section measured the amount of sick days the participant may have had, presuming that he/she was in employment. In any retrospective assessment there is a trade-off between recall accuracy and obtaining a representative measure of service use. Although one option would have been to assess service use over the whole intervening periods between assessments, this was not conducted, as there were concerns that this would result in a loss of accuracy of the data. Given that many of the participants would have had their condition for a prolonged period of time, it was assumed that service use would be relatively stable. Consequently, only the previous month was assessed at both the end-of-treatment and 6-month follow-up stages. For the purposes of this investigation, informal care was not assessed, given concerns that there would be no way to obtain robust measures in this context.

Service use measured with the CSRI was combined with relevant unit costs[52,53] to derive total costs. These costs include salary components, capital and administrative overheads and training, and are reported in terms of face-to-face contact time with participants. The costs of the interventions were calculated using a bottom-up microcosting approach, based on the time spent by professionals providing the intervention (instructors), training (consultant psychiatrist) and supervision (therapist supervisor). The costs were divided by the typical number of people attending a group (eight). The cost of one BPT or Pilates session was £9, whereas training and supervision for the BPT instructors were estimated at £44.14 per participant receiving the intervention.

In the original protocol, an assessment of non-verbal communication and gestural behaviours, using the NEUROGES-ELAN system, was proposed.[54] The NEUROGES-ELAN system is a coding and annotation tool that is designed to analyse gestural behaviour. However, because of the difficulties in implementation, gestural and non-verbal communicative behaviours were instead captured on an observational basis using the CAINS expressive subscale.[37]

Blinding and randomisation

Randomisation was conducted by the Pragmatic Clinical Trials Unit (PCTU) based at Queen Mary University of London [Clinical Trials Unit (CTU) Reg: 32], independent of the research team using a computer-generated sequence. Participants were randomly allocated with equal probability to the intervention or control group, stratified by region, in batches using randomly permuted blocks of four and six, beginning each batch at the start of a new block to preserve balance. The Chief Investigator, all assessors and the trial statistician were blinded to the treatment allocation until all end-of-treatment data were collected and the statistical analysis plan was signed off. In order to prevent bias, eligibility and baseline assessments took place prior to randomisation. Prior to each meeting with the research assistant, participants were reminded not to disclose any details of the intervention in which they took part. In the event of unmasking, this was recorded, specifying whether or not this occurred before or after the primary outcome measure (the PANSS assessment) was completed.

Procedures

Participants were recruited from NHS mental health community services in five different Trusts: Mersey Care NHS Trust, Greater Manchester West Mental Health NHS Foundation Trust, North East London NHS Foundation Trust, South London and Maudsley NHS Foundation Trust, and East London NHS Foundation Trust. The study was presented to clinical mental health teams, assertive outreach teams, recovery and rehabilitation teams, early intervention services and clinicians who run the outpatient clinics in the area, in order to provide information regarding the nature of the study. These clinicians were then asked to identify all patients with a diagnosis of schizophrenia who had not recently changed their antipsychotic medication and were presenting with negative symptoms, and to ask these patients for their consent to be approached by a researcher. The clinicians who approached these potential participants were typically psychiatrists, community psychiatric nurses or social workers, depending on the clinical setting from which the participant was recruited. On the patient's agreement, the researcher would then contact him/her to arrange a meeting, during which he/she would be given an information sheet and an explanation of the trial. Assessments were completed either in the patient's home, local community treatment sites or on university premises. After the patient had provided informed consent, a full PANSS assessment was then conducted to establish whether or not he/she had a rating of at least 18 on the negative symptoms subscale, as per the inclusion criterion, before being formally recruited onto the trial. When participants gave their consent, eligibility relating to diagnosis and medication history was confirmed, based on their medical records. Once approximately 16 participants at the study site were recruited, researchers then recontacted patients in order to arrange a second meeting, during which the full baseline assessment was conducted, including a second PANSS assessment. All assessments occurred

within 1 month of the arranged group start date. The duration of the assessments ranged from approximately 30 to 120 minutes, and the assessments were conducted either in the patient's home, local community mental health services or university premises.

After completion of the baseline assessments, the assigned trial ID numbers would be passed to a statistician at the PCTU for randomisation. Once randomised, the relevant names, contact details and any necessary risk information was then passed on to the Pilates instructor or BPT (depending on their allocation) via the trial manager, who was the only research team member who was unblinded to treatment allocations. The trial manager was not in direct contact with any participants, and was not involved in any of the assessments that were completed. The cofacilitators then contacted the patients to assist in the logistics of attending the groups, arranging taxi support if required. All of the groups took place in local community hospitals, civic buildings, community arts spaces and disability support centres. The design, implementation and the nature of the settings in which the groups took place remained largely consistent throughout the duration of the study.

On completion of the BPT and Pilates groups, the researchers contacted the patients again in order to complete an end of treatment assessment, which was required to be completed within 1 month of the groups finishing. The end of treatment assessment involved all of the structured interviews and questionnaires included in the baseline assessment CRF, in addition to the CSQ which was used to measure the participants' satisfaction with treatment. Six months after completion of the intervention, the final follow-up assessment was conducted, which, again, included all of the same interviews and questionnaires from the baseline assessment. Participants were paid £25 expenses for each assessment interview that they attended.

Treatment and control conditions

Both BPT as the treatment condition and Pilates as the active control were delivered in 20 sessions of 90 minutes each, over a 10-week period, with two sessions each week, held on non-consecutive days. Twenty sessions was deemed appropriate, given that this is the length that is specified in the manual, and this has been found to be sufficient in two trials[17,55] evaluating BPT as a treatment for severe mental illness, and, in a review on music therapy, 16 sessions were sufficient to result in medium effect-sized improvements in negative symptoms.[56] Dependent on the randomisation, between 7 and 10 participants were assigned to each BPT group or Pilates class, respectively. To limit the impact of any one body – psychotherapist or Pilates instructor – on outcomes, each one was permitted to run a maximum of only two groups.

Treatment condition

The treatment under investigation was BPT, as outlined in an updated version of the manual used in the 2006 exploratory trial.[17,57] The main goals of BPT as a treatment for negative symptoms in chronic schizophrenia are to reconstruct a coherent ego structure through grounding and bodily awareness; strengthen self-referential processes as a prerequisite for safe social interaction and reality testing; widen and deepen the range of emotional responses to environmental stimuli; improve boundary demarcation, enabling differentiation between self and other; and help patients to explore a range of expressive and communicative behaviours, with the aim of reducing emotional withdrawal and improving prosocial capabilities.

Each of the 20 sessions comprised five discrete sections. The first part was the opening circle, which aimed establish the group as a therapeutic space, facilitate basic communication between participants, and draw participants' focus towards the body. Typical activities included breathing exercises, structured communication activities and self-massage. The second section was the warm-up, which aimed to promote self-awareness, emotional stimulation and reality-testing. In this section the focus is on physical movements, exploring the personal kinesphere, general space and physical sensations. The third section included structured tasks, aimed to address specific body image disturbances, such as boundary loss and

desomatisation. Techniques adopted included mirroring tasks, body sculpturing using ropes or art materials and group tasks used to explore distinction between self and other. The fourth section centred on creativity, including activities that support participants to use their bodies and movement as a source of expression and pleasure. Tasks in this section included dancing, creating music or collage, or other elements of play using various objects. In the final section, the closing circle, the time is used to disengage from the therapy, and reflect on any events, thoughts or feelings that may have been brought up by the session.

Each BPT group was facilitated by an Association of Dance Movement Psychotherapy (ADMP)-accredited therapist, who had attended an additional two-day training course in delivering the intervention in its manualised form. In each group the therapist was supported by a volunteer as cofacilitator. Each therapist and cofacilitator received a minimum of three supervision sessions by a senior dance movement psychotherapist over each group, either in person or via video link. In two cases, a fourth supervision session was held in order to address specific issues that arose as the groups were ongoing. At the end of every session, therapists completed a BPT session guide sheet (see *Appendix 1*) to assist in reviewing the session and planning for the next. The principal aim of this exercise was to further encourage adherence to the manual.

Adherence to the manual was assessed using a specifically developed adherence scale (see *Appendix 2*) that was administered by body psychotherapists who were trained in assessing the sessions. A total of four sessions, spanning one from each quartile, was selected from each group in order to ensure the continuity of adherence over the whole 20-session treatment. Given that the first and final sessions adopted a slightly different structure to the norm (the first session focused primarily on introducing the method to participants, whereas the final session focused on planning for afterwards), they were omitted from the adherence rating. In order to allow for the aspects of the intervention that relate specifically to group process to be rated, only groups with a minimum of three participants in attendance were considered for adherence rating. The scale assesses whether 10 core components of BPT have been implemented, with a score of 0, 1 or 2 (no, limited, definite implementation) for each component. The total score ranges therefore from 0 to 20.

Control condition

In order to mirror the structure of the BPT condition as closely as possible, the Pilates group was also a 90-minute, 20-session, twice-a-week intervention, which was held on non-consecutive days. The Pilates group was described to patients as a fitness and physical health intervention, with the intention to limit the risk of different acceptance rates of the two interventions once patients are informed about their allocation. All of the classes were held in the same venues as the BPT groups.

Each class was facilitated by a Register of Exercise Professionals (REPS) level 3-qualified Pilates instructor and assisted by a cofacilitator. Prior to the classes starting, a brief training session was arranged between the instructor and an experienced clinician. During this meeting the instructors were provided with an outline of the study, an explanation of what schizophrenia and negative symptoms are, what to typically expect in the groups, and what to do if any untoward events or potential risk issues emerged. On any occasions on which it was felt that the Pilates instructor may benefit from additional support, an additional supervision session with an experienced clinician was arranged outside of the classes.

Prior to the groups starting, a brief Pilates guide was developed by the research team in collaboration with instructors who were involved in the trial (see *Appendix 3*), using the Pilates Union Matwork Manual as a guide.[58] The intervention guide provided a brief summary of how to run the groups and a loosely structured exercise plan, allowing for considerable flexibility to accommodate differing fitness levels between participants. The use of props (other than mats and head blocks), music and additional activities designed to encourage group interactions was not permitted. Instructors were advised to pay attention to patients and respond to them without addressing or verbalising emotions and without promoting group interactions, if possible.

Sample size calculation

A 20% reduction in the PANSS score has been used as an indicator of clinically significant improvement in the past,[59] which, if applied specifically to the negative symptoms subscale, would equate to a difference of between 3 and 4 points, given the eligibility criteria. To detect a difference of 3 points with a standard deviation (SD) of 5, with 90% power for 5% significance, 58 patients were required in each arm. To allow for clustering by group, an intraclass correlation coefficient (ICC) for treatment group of 0.1, and seven patients per group with analysable data at the end of treatment, gives an inflation factor of 1.6, meaning that 93 participants in each arm were required. At 6 months we predicted a loss to follow-up of 31%, so recruiting 256 participants would leave 88 per arm at 6 months, and 91% power to detect a difference of 3 points at this time point. One hundred and twenty-eight patients per arm, i.e. 16 groups of approximately eight patients in each arm, would give 94% power for the end-of-treatment analysis, assuming that 87.5% of patients have analysable data.

Analysis plan

Prior to conducting the analysis, an analysis plan was drafted by the trial statistician. The primary analysis was of available cases of the PANSS negative subscale at the end of treatment, following intention-to-treat principles. We used a mixed-effects model fitted by restricted maximum likelihood with fixed effects for the treatment group, baseline PANSS negative scores (because it was expected to be highly correlated with the outcome at end of treatment, so increasing the precision of the estimated treatment effect) and centre (because it was used to stratify the randomisation), and random effects for therapy groups to allow for clustering by group. Secondary outcomes were analysed using the same approach. To evaluate the impact of missing data in a sensitivity analysis, multiple imputation of the data set was performed and the analysis was replicated. The data were exported from Stata version 12 (StataCorp LP, College Station, TX, USA) and missing data were multiply imputed in REALCOM-IMPUTE software[60] to give 10 completed data sets, using a multilevel model with therapy groups included as a random effect. These were imported back into Stata, analysed and the results pooled using Rubin's rules. Depending on whether or not the outcomes were continuous, count or ordinal in nature, Stata's *xtmixed* or *xtmepoisson* commands were used. In all of the analysis, completed statistical significance was determined at $p < 0.05$.

In order to assess the impact of BPT in those who complied with treatment, a simple complier-average causal effect (CACE) analysis was completed on all scales, which report a continuous outcome score (the PANSS, CAINS, SAS, Calgary Depression Scale, MANSA and SIX). In contrast with the rest of the analysis, a multilevel model was not adopted. Compliance was originally defined as attending at least 10 sessions; however, this was reduced to five sessions prior to the analysis plan being signed off following a recent study[55] evaluating the effectiveness of BPT for chronic depression, which found a significant effect of treatment at this threshold.

In the final part of the analysis, preplanned subgroup analyses were conducted on the PANSS negative subscale, the CAINS expressive and experiential subscales and the Calgary Depression Scale by fitting an interaction term between the moderator of interest and the treatment group. The differences in treatment response were explored between those with higher negative symptoms at baseline and a longer duration of illness. High symptoms were defined as a score of > 23 on the PANSS negative subscale, whereas a low score was ≤ 23. In an examination of the possible effect of duration of illness, two different cut-offs were used. In the first analysis, participants with a duration of illness of > 5 years and ≤ 5 years were compared, and, in the second analysis, those with a duration of illness of > 15 years and ≤ 15 years were compared. All analysis was completed using Stata.

Economic analysis plan

A health and social care perspective was adopted in the analyses, in line with NICE recommendations. Costs were compared for the groups using a bootstrap regression model to account for non-normality in the distribution of cost data. Missing costs and QALY data were imputed using a regression-based method to estimate missing values based on other variables in the data set. The economic analysis was completed by a health economist who was independent to the trial statistician.

Cost-effectiveness was assessed by estimating an incremental cost-effectiveness ratio (ICER) to show the extra cost incurred by BPT to generate one extra QALY. This is defined as the cost difference divided by the outcome difference, after adjusting for costs and outcomes measured at baseline. This is most meaningful in the event of BPT being more (less) expensive and more (less) effective than Pilates; otherwise, one of the alternatives is dominant (less expensive and better). However, there will inevitably be uncertainty around the cost and outcome differences. To deal with uncertainty around the ICER, a cost-effectiveness plane (CEP) and cost-effectiveness acceptability curves (CEACs) were created. For the CEP, 1000 bootstrapped estimates of cost and outcome differences were produced, adjusted for baseline and plotted these against each other. This then showed the probability that BPT had (1) higher costs and better outcomes; (2) higher costs and worse outcomes; (3) lower costs and worse outcomes; or (4) lower costs and better outcomes than Pilates. The CEAC was produced using the net benefit approach, for which the QALY difference is multiplied by the societal value (threshold) placed on a QALY and the incremental service cost is subtracted. A positive incremental net benefit means that BPT is more cost-effective and the proportion of positive values for each societal QALY value gives the probability that BPT is cost-effective at that threshold.

In this study, the cost-effectiveness of receiving BPT rather than Pilates was examined. Both BPT and Pilates are delivered by a therapist/instructor and in groups, so we estimated costs for both interventions. However, in routine practice, BPT is likely to be considered as an additional service, rather than as an alternative to other active therapies such as Pilates. Consequently, in a sensitivity analysis, the impact of removing the Pilates group costs from the total costs in the control arm was explored.

Ethical considerations

The study received ethical approval from by the Camden and Islington National REC (REC reference 10/H0722/44) on 13 July 2010. The trial was overseen by an independent Data Monitoring and Ethics Committee (DMEC), which reported to a TSC that was established prior to the trial start date. The TSC consisted of researchers with experience of trial design and implementation in psychosis, a statistician and a service user who had previously undergone a treatment of BPT.

During the study, all of the data were stored in line with the Data Protection Act and all video-recorded data were encrypted and password protected on hard disk drives, which were locked in file cabinets. On completion of the project, all of the data have been archived for a period of 25 years. In both study arms, participants received input in addition to their treatment, and their standard care was not compromised at any time. All patients were initially approached by a clinician who asked for their consent before they were contacted by a researcher. Once contacted, all potential participants were fully informed about the study and asked for written informed consent prior to enrolment.

Patient and public involvement

Patient and public involvement came principally in the form of trial oversight. The TSC included a service user who had previously attended a BPT group similar in nature to the therapy evaluated in the current investigation. This service user provided input on which outcomes would be important to evaluate, and reviewed the appropriateness of the measures used to evaluate these outcomes. In addition, they provided input on the settings in which both of the assessments and groups should take place, emphasising the importance of consistency throughout.

Chapter 3 Results

Participant recruitment and retention

The participant study dropout at each stage of the project is presented in the CONSORT (Consolidated Standards of Reporting Trials) diagram (*Figure 1*). Recruitment took place from December 2011 until June 2013. In the study it was necessary to screen a far higher number of potential participants than anticipated in order to recruit the required number. In total, 1371 individuals were identified as potentially eligible, but, in the end, only 356 were recruited, of which 275 were randomised. This was due to a number of factors. First, a relatively large number of screened patients were found to be ineligible, either because of the potential participant subsequently being found to have a diagnosis of schizoaffective disorder or the severity of negative symptoms being below the eligibility threshold. Second, given the group design of the study once all of the therapy/control places were provisionally filled, no more participants were approached unless a participant subsequently dropped out. Consequently, a number of participants were initially screened as potentially eligible, but were not approached owing to the lack of available spaces on the trial in their area. A relatively large number of potential participants declined to take part; however, given the nature of the groups, the typical symptom presentation of the patients who would be eligible, and the requirement to attend a group twice a week at specified times, this figure would not be considered excessive.

Following randomisation, the study attrition rate was lower than anticipated. Of the 275 randomised, 266 (96.7%) were assessed at end of treatment and 255 (92.7%) went on to complete the 6-month follow-up. In both cases this was significantly higher than the retention figures that were proposed in the protocol and used for the sample size calculation. One participant died after completion of the groups as a result of an illness that was not related to the intervention, and did not complete either the end-of-treatment or 6-month follow-up assessment. The data of this participant were omitted, leaving a final total of 274 participants who were potentially included in the analysis, presuming data availability.

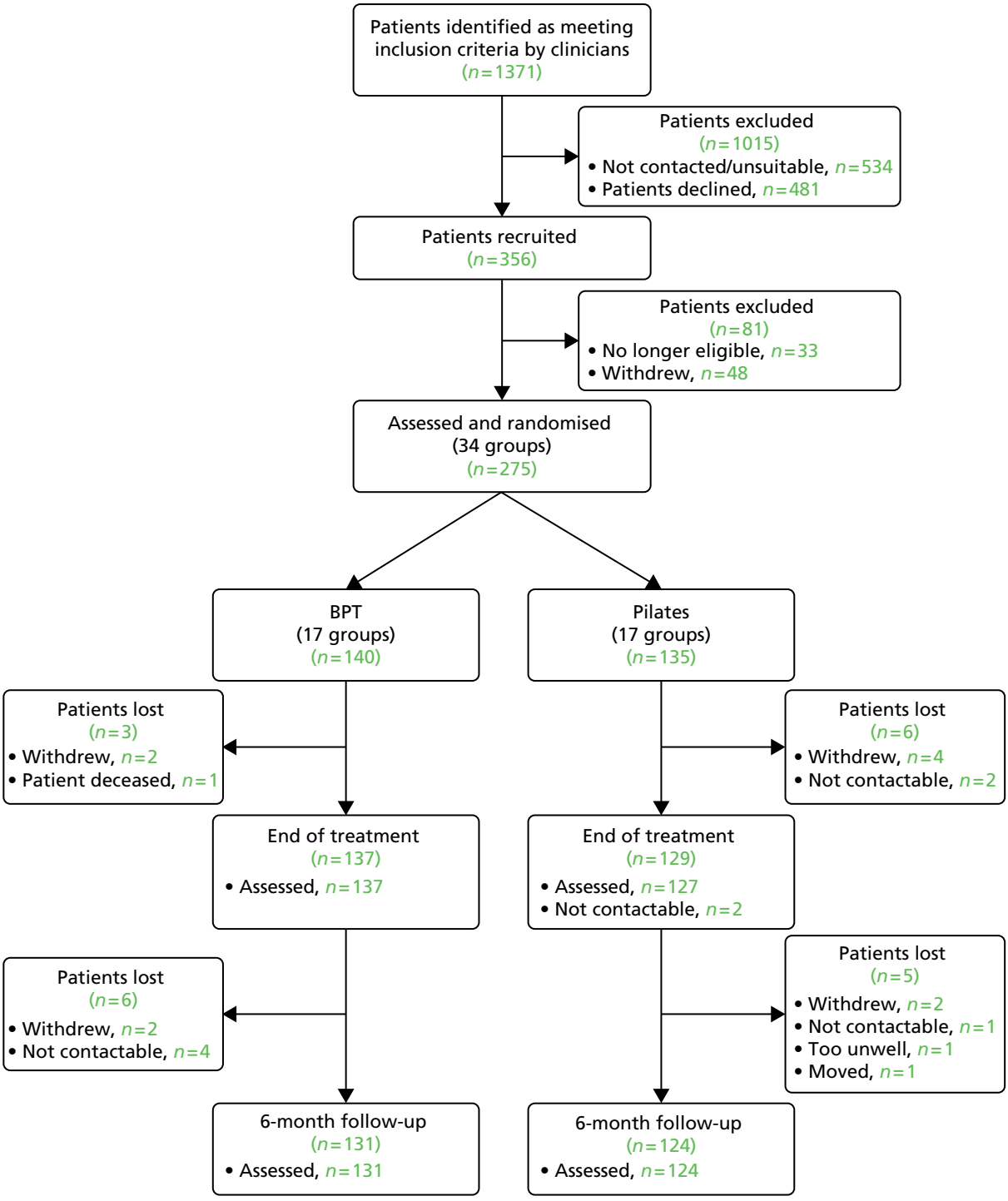

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) diagram.

Baseline characteristics

The baseline sociodemographic characteristics of the sample are presented in *Table 1*. Study participants were, on average, 42.2 years old (SD = 10.7 years) and predominantly male (74%), unemployed (96%) and living alone (57%). The baseline outcome scores for the whole sample are presented in *Table 2*. The participants presented with moderate levels of negative symptoms (PANSS negative subscale score = 23.2, SD = 4.3), mild positive symptoms (PANSS positive subscale score = 14.1, SD = 4.9) and low to moderate symptoms of depression (Calgary Depression Scale score = 4.7, SD = 4.4). The level of inter-rater reliability for the PANSS was high (PANSS total ICC = 0.85). Assessor blinding was maintained prior to the primary outcome assessment in over 249 out of 264 of cases (94.3%).

TABLE 1 Descriptive statistics of participant characteristics at baseline, for experimental and control conditions

Variable	BPT (*N* = 140)	Pilates (*N* = 135)	Total (*N* = 275)
Centre, *n* (%)			
East London[a]	41 (29)	40 (29)	81 (29)
North East London[a]	8 (6)	8 (6)	16 (6)
South London	36 (26)	32 (24)	68 (2)
Manchester	23 (16)	23 (17)	46 (17)
Liverpool	32 (23)	32 (24)	64 (23)
Age (years) mean (SD)	41.1 (10.1)	43.3 (11.1)	42.2 (10.7)
Gender, *n* (%)			
Male	103 (74)	100 (74)	203 (74)
Female	37 (26)	35 (26)	72 (26)
Ethnicity, *n* (%)			
White	71 (52)	67 (53)	138 (52)
Black	39 (29)	38 (30)	77 (29)
Asian	13 (9)	16 (13)	29 (11)
Other	14 (10)	6 (5)	20 (8)
Employment, *n* (%)			
Unemployed	131 (94)	132 (98)	263 (96)
Other	8 (6)	3 (2)	11 (4)
Living situation, *n* (%)			
Alone	83 (60)	73 (54)	156 (57)
With others	56 (40)	62 (46)	118 (43)
Number of children, median (IQR)	0 (0–1)	0 (0–1)	0 (0–1)
Duration of illness (years), median (IQR)	11 (7–18)	10 (7–19)	11 (7–18)
Number of hospitalisations, median (IQR)	3 (1–5.5)	3 (2–5)	3 (1–5)
Medication: defined daily dose,[b] mean (SD)	1.48 (1.11)	1.71 (1.28)	1.59 (1.20)

IQR, interquartile range.
a These two centres were treated as one for the purposes of the stratified randomisation.
b Defined daily dose: 1.00 = average maintenance daily dose for a drug used for its main indication. Only antipsychotic medication considered.

TABLE 2 Baseline outcome measures of the study sample

Outcome	BPT group ($N = 140$)			Pilates ($N = 135$)			Total ($N = 275$)		
	n *(%)*	*Mean*	*SD*	n *(%)*	*Mean*	*SD*	n *(%)*	*Mean*	*SD*
PANSS									
Negative	140 (100)	23.3	4.3	135 (100)	23.1	4.4	275 (100)	23.2	4.3
Positive	138 (99)	14	5.1	135 (100)	14.1	4.7	273 (99)	14.1	4.9
General	137 (98)	32.9	8.3	133 (99)	32.5	8.1	270 (98)	32.7	8.2
Total	135 (96)	70.1	13.6	133 (99)	69.5	13.3	268 (97)	69.8	13.4
PANSS Marder negative	140 (100)	20.7	5.7	135 (100)	20.3	5.1	275 (100)	20.5	5.4
CAINS									
Experience	136 (97)	22.1	5.6	134 (99)	21.5	5.5	270 (98)	21.8	5.6
Expression	140 (100)	8	3.5	133 (99)	7.5	3.9	273 (99)	7.8	3.7
Calgary Depression Scale	140 (100)	4.8	4.2	134 (99)	4.6	4.6	274 (99)	4.7	4.4
MANSA	126 (90)	53.4	11.6	126 (93)	52.7	10.9	252 (92)	53	11.2
SAS	128 (94)	1.7	2.1	126 (93)	2.3	2.7	254 (92)	2	2.5
SIX	140 (100)	2.4	1.1	135 (100)	2.3	1.1	275 (100)	2.4	1.1
	n *(%)*	*Median*	*IQR*	n *(%)*	*Median*	*IQR*	n *(%)*	*Median*	*IQR*
SNS									
Friends seen	133 (95)	1	0.0–2.0	129 (96)	1	0.0–2.0	262 (95)	1	0.0–2.0
Family seen	133 (95)	2	1.0–3.0	129 (96)	2	1.0–4.0	262 (95)	2	1.0–3.0
Others seen	133 (95)	0	0.0–1.0	129 (96)	0	0.0–1.0	262 (95)	0	0.0–1.0
Total seen	133 (95)	4	2.0–5.0	129 (96)	4	2.0–5.0	262 (95)	3	2.0–5.0
TUS									
Number of activities	139 (99)	3	1.0–6.0	135 (100)	3	1.0–6.0	274 (99)	3	1.0–6.0
Time spent (hours)	139 (99)	1.5	0.0–3.5	135 (100)	1.8	0.3–4.0	274 (99)	1.6	0.2–3.8

IQR, interquartile range.

Uptake of interventions

The number of BPT and Pilates sessions attended are presented in *Table 3*. In the BPT arm, 106 participants (75.7%) attended at least 5 of the 20 sessions, thus fulfilling the minimum attendance threshold required to be defined as a treatment complier in the CACE analysis. It was estimated that approximately 25% of participants were provided with taxis to support attendance.

TABLE 3 Number of sessions attended by those randomised to a group

Number of sessions attended	BPT group ($N = 140$)	Pilates group ($N = 135$)	Total ($N = 275$)
0, *n* (%)	11 (8)	18 (13)	29 (11)
1–5, *n* (%)	30 (21)	40 (30)	70 (25)
6–14, *n* (%)	45 (32)	42 (31)	87 (32)
15–20, *n* (%)	54 (39)	35 (26)	89 (32)
Median number attended (IQR)	11 (5–17)	8 (1–15)	9 (2–17)

IQR, interquartile range.

Therapist adherence to manual

Of the 17 different BPT groups, 16 were assessed for adherence to the manual using the BPT Adherence Scale (see *Appendix 2*). One group was not assessed because of the lack of video data available for the sessions. In total, 64 sessions (18.8% of all sessions conducted) were assessed. Overall, the therapist adherence to the manual was relatively high, with a mean score of 17.6 out of the maximum of 20 (SD = 0.21). In all of the groups there was evidence that the body psychotherapists were able to follow the structure of the sessions as laid out in the manual, and establish a safe and cohesive therapeutic environment. Areas that were less consistently implemented related to how the exercises completed related specifically to negative symptoms, and the introduction of coping strategies that were designed to deal with negative symptoms specifically.

Primary outcome

The main outcomes of the trial are shown in *Table 4*. There was a small reduction in mean PANSS negative symptoms between baseline and end of treatment in both the BPT and Pilates groups (within-group mean reduction in the BPT group = 1.5, SD = 3.5; Pilates group = 1.5, SD = 3.8). After controlling for baseline scores, study centre and therapy group, no significant difference between the treatment and control condition was detected [adjusted difference in means = 0.03, 95% confidence interval (CI) –1.11 to 1.17; $p = 0.959$, model-based ICC = 0.099].

Secondary outcomes

Significant reductions in mean SAS (–0.65, 95% CI –1.13 to –0.16; $p = 0.009$, ICC < 0.001) and mean CAINS expression subscale (–0.62, 95% CI –1.23 to 0.00; $p = 0.049$, ICC = 0.022) were detected in the BPT group compared with the Pilates group at the end of treatment. No other significant differences were found in the secondary outcomes at this stage. In both groups, participants reported a high level of satisfaction with the treatment they received (BPT CSQ = 25.3, SD = 4.6; Pilates CSQ = 25.9, SD = 4.0).

At the 6-month follow-up, no significant difference in means in the PANSS negative symptoms subscale score was detected between the BPT and Pilates study arms (–0.18, 95% CI –1.68 to 1.32; $p = 0.812$, ICC = 0.137). There was a significant difference in mean SAS scores at 6-month follow-up (–0.50, 95% CI –0.97 to –0.07; $p = 0.028$, ICC ≤ 0.001). No other significant differences were detected on any other outcome at follow-up.

TABLE 4 Outcomes at end of treatment and 6-month follow-up in the BPT and Pilates groups, using an available case analysis

	BPT group						Pilates group							
	Baseline		End of treatment		6 months		Baseline		End of treatment		6 months		Adjusted difference in means/IRR at end of treatment (95% CI)[b,c]	Adjusted difference in means/IRR at 6 months (95% CI)[b,c]
Outcome[a]	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
PANSS														
Negative ($n = 254$)	23.3	4.3	21.8	5.4	21.7	5.7	23.1	4.4	21.5	4.7	21.7	5.1	0.03 (–1.11 to 1.17), ICC 0.099	–0.18 (–1.68 to 1.31), ICC 0.137
Positive ($n = 253$)	14	5.1	13.1	4.7	13.4	4.7	14.1	4.7	13.3	4.2	13.6	4.9	0.06 (–0.71 to 0.84), ICC < 0.001	–0.12 (–1.03 to 0.79), ICC < 0.001
General ($n = 249$)	32.9	8.3	30.2	8	30.1	8.1	32.5	8.1	29.9	7.3	30.4	7.5	0.32 (–1.31 to 1.94), ICC 0.096	–0.70 (–3.07 to 1.67), ICC 0.205
Marder negative ($n = 253$)	22.2	4.7	20.7	5.7	20.2	5.7	21.9	5	20.3	5.1	20.1	5.6	0.23 (–0.86 to 1.32), ICC 0.678	0.04 (–1.38 to 1.45), ICC 0.075
CAINS														
Experience ($n = 246$)	22.1	5.6	20.5	5.8	20.8	6.7	21.5	5.5	19.8	5.8	20.6	6.2	0.05 (–1.13 to 1.22), ICC 0.037	–0.04 (–1.48 to 1.40), ICC 0.041
Expression ($n = 253$)	8	3.5	7.3	3.7	7.1	4	7.5	3.9	7.5	4.1	7.1	4.3	–0.62 (–1.23 to 0.00), ICC 0.022[d]	–0.27 (–1.05 to 0.50), ICC 0.023
Calgary ($n = 253$)	4.8	4.2	3.9	4.3	4.1	4.1	4.6	4.6	3.9	4.3	4.2	4.2	–0.01 (–0.72 to 0.71), ICC < 0.001	–0.20 (–1.18 to 0.79), ICC 0.086
MANSA ($n = 254$)	4.4	0.9	4.5	0.9	4.6	1	4.4	0.9	4.6	0.9	4.5	0.9	–0.11 (–0.27 to 0.58), ICC < 0.001	0.10 (–0.12 to 0.32), ICC 0.050
SNS[e] ($n = 232$)														
Relatives seen	2	1.0–3.0	3	1.0–4.0	2	1.0–4.0	2	1.0–4.0	2	1.0–4.0	2	1.0–4.0	1.13 (0.89 to 1.32)	0.96 (0.80 to 1.15)
Friends seen	1	0.0–2.0	1	0.0–2.0	0.5	0.0–2.0	1	0.0–2.0	1	0.0–2.0	1	0.0–2.0	0.94 (0.80 to 1.42)	0.91 (0.63 to 1.30)
Total number seen	3	2.0–5.0	4	3.0–6.0	4	2.0–6.0	4	2.0–5.0	4	3.0–6.0	4	2.0–6.0	0.83 (0.69 to 1.14)	0.97 (0.85 to 1.12)

	BPT group						Pilates group							
	Baseline		End of treatment		6 months		Baseline		End of treatment		6 months		Adjusted difference in means/IRR at end of treatment (95% CI)[b,c]	Adjusted difference in means/IRR at 6 months (95% CI)[b,c]
Outcome[a]	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
TUS[e] ($n = 254$)														
Number of activities	3	1.0–6.0	3	1.0–7.0	3	1.0–7.0	3	1.0–6.0	2	1.0–7.0	2	1.0–7.0	1.03 (0.89 to 1.42)	1.04 (0.81 to 1.33)
Time spent (hours)	1.5	0.0–3.5	1.5	0.3–4.0	1.5	0.0–3.0	1.8	0.3–4.0	2	0.3–4.5	1.5	0.2–3.8	1.03 (0.80 to 1.32)	0.96 (0.73 to 1.25)
SAS ($n = 229$)	1.7	2.1	1.2	1.7	1.2	1.5	2.3	2.7	2.1	2.9	1.9	2.4	–0.65 (–1.13 to –0.16), ICC < 0.001[d]	–0.50 (–0.94 to –0.07), ICC 0.007[d]
SIX ($n = 254$)	2.4	1.1	2.5	1.1	2.5	1	2.3	1.1	2.5	1.1	2.5	1.2	–0.02 (–0.17 to 0.20), ICC < 0.001	–0.10 (–0.27 to 0.08), ICC < 0.001
CSQ ($n = 237$)	–	–	25.3	4.6	–	–	–	–	25.9	4	–	–	–0.68 (–1.80 to 0.44)	–

IQR, interquartile range; IRR, incidence rate ratio.

a Data within parentheses denote the number of participants completing each outcome at 6 months (CSQ at end of treatment).

b In the PANSS, CAINS, Calgary Depression Scale and SAS, a negative score represents a result in favour of BPT. In the MANSA, SNS, TUS, SIX and CSQ a negative value represents a result in favour of BPT.

c Models adjusted for baseline measure of outcome, study centre and a random effect for therapy group (except CSQ). ICC value denotes the model-based ICC.

d Denotes significance at $p < 0.05$.

e Median, IQR and IRR reported.

Ancillary analyses

Analysis following imputation

Multiple imputation of the data set was performed and the analysis was replicated in order to evaluate the impact of missing data. During the study there was minimal participant dropout and, when the assessment was conducted, the full assessment was completed in almost all of the cases. Consequently, only minimal differences between the analysis of the imputed and non-imputed data sets were noted. The findings are reported in *Table 5*.

TABLE 5 Adjusted differences in means between the groups at end of treatment and 6-month follow-up, using the imputed data sets (intention-to-treat analysis)

Outcome ($n = 274$)	Adjusted difference in means/IRR at end of treatment (95% CI)[a]	Adjusted difference in means/IRR at 6 months (95% CI)[a]
PANSS[a]		
Negative	0.09 (–1.08 to 1.25), ICC 0.102	–0.09 (–1.58 to 1.39), ICC 0.135
Positive	0.07 (–0.70 to 0.84), ICC < 0.001	–0.19 (1.14 to 0.76), ICC < 0.001
General	0.26 (–1.38 to 1.89), ICC 0.087	–0.58 (–2.93 to 1.76), ICC 0.202
Marder negative	0.18 (–0.93 to 1.28), ICC 0.752	0.09 (–1.37 to 1.55), ICC 0.083
CAINS		
Experience	–0.3 (–1.34 to 1.28), ICC 0.069	–0.10 (–1.58 to 1.38), ICC 0.056
Expression	–0.60 (–1.22 to 0.02), ICC 0.026	–0.30 (–1.06 to 0.50), ICC 0.031
Calgary Depression Scale	0.00 (–0.74 to 0.75), ICC > 0.001	–0.17 (–1.17 to 0.84), ICC 0.087
MANSA	–0.17 (–0.37 to 0.02), ICC 0.033	0.07 (–0.20 to 0.34), ICC 0.074
SNS (IRR)[b]		
Relatives seen	0.96 (0.81 to 1.14)	0.99 (0.77 to 1.27)
Friends seen	0.89 (0.62 to 1.27)	0.84 (0.60 to 1.18)
Total no. seen	0.97 (0.83 to 1.14)	1.00 (0.83 to 1.20)
TUS (IRR)[b]		
Number of activities	1.11 (0.85 to 1.44)	1.05 (0.78 to 1.42)
Time spent (hours)	1.00 (0.74 to 1.36)	0.98 (0.72 to 1.34)
SAS	–0.62 (–1.15 to –0.09) to ICC < 0.001[c]	–0.58 (–1.07 to –O.09), ICC < 0.001[c]
SIX	–0.03 (–0.17 to 0.12) to ICC < 0.001	–0.09 (–0.27 to 0.09), ICC 0.002

IQR, interquartile range; IRR, incidence rate ratio.
a Models adjusted for baseline measure of outcome, study centre and a random effect for therapy group (except CSQ). ICC value denotes the model-based ICC where relevant.
b Median, IQR and IRR reported.
c Denotes significance at $p < 0.05$.

In the PANSS negative subscale, no significant difference was detected between the experimental and control condition either at the end of treatment (adjusted difference in means = 0.09, 95% CI –1.08 to 1.26; $p = 0.885$, ICC = 0.102) or the 6-month follow-up stage (adjusted difference in means = –0.09, 95% CI –1.58 to 1.39; $p = 0.902$, ICC = 0.135). In the secondary outcomes at end of treatment, extrapyramidal symptoms were found to be significantly lower in the BPT arm (adjusted difference in means –0.62, 95% CI –1.15 to –0.09; $p = 0.021$, ICC < 0.001). In contrast with the available case analysis, the difference in the CAINS experience was not significant at the 5% level, despite only a minimal change in the estimate (–0.60, 95% CI –1.22 to 0.02; $p = 0.056$, ICC = 0.026). At the 6-month follow-up, no significant differences were detected between BPT and Pilates, other than in extrapyramidal symptoms (–0.58, 95% CI –1.07 to –0.09; $p = 0.021$, ICC = 0.001).

Complier-average causal effect analysis

To estimate the causal effect of treatment accounting for departures from the randomised intervention, a CACE analysis was conducted, using a minimum attendance of 5 and 10 BPT sessions to define those who complied with treatment. The minimum attendance of five sessions was prespecified and the minimum of 10 sessions was exploratory in nature. The results are presented in *Table 6*, including both the estimates for both 5 and 10 sessions as an indicator of compliance. In the primary outcome at end of treatment, no significant adjusted difference in mean PANSS scores between BPT and Pilates was detected (–0.13, 95% CI –1.41 to 1.64). In the secondary outcomes, only a significant difference in means in the SAS was detected (–0.82, 95% CI –1.51 to –0.12).

TABLE 6 Complier-average causal effect analysis estimates, using a minimum of 5 and 10 sessions of BPT attendance as an indicator of compliance

		CACE: coefficient (95% CI)	
Outcome	ITT: coefficient (95% CI)	Minimum 5 sessions	Minimum 10 sessions
PANSS			
Negative	0.09 (–1.08 to 1.25)	0.11 (–1.41 to 1.64)	0.15 (–1.89 to 2.19)
Positive	0.07 (–0.70 to 0.84)	0.09 (–0.93 to 1.11)	0.12 (–1.23 to 1.48)
General	0.26 (–1.38 to 1.89)	0.34 (–1.81 to 2.49)	0.45 (–2.41 to 3.31)
Marder negative	0.18 (–0.93 to 1.28)	0.23 (–1.22 to 1.69)	0.31 (–1.62 to 2.25)
CAINS			
Experience	–0.03 (–1.34 to 1.28)	–0.04 (–1.76 to 1.68)	–0.06 (–2.35 to 2.24)
Expression	–0.60 (–1.22 to 0.02)	–0.79 (–1.60 to 0.02)	–1.05 (–2.15 to 0.03)
Calgary Depression Scale	0.00 (–0.74 to 0.75)	0.00 (–0.97 to 0.98)	0.01 (–1.30 to 1.31)
CSQ	–0.83 (–2.05 to 0.40)	–1.09 (–2.70 to 0.53)	–1.45 (–3.60 to 0.70)
SAS	–0.62 (–1.15 to –0.09)[a]	–0.82 (–1.51 to –0.12)[a]	–1.09 (–2.02 to –0.16)[a]
SIX	–0.03 (–0.17 to 0.12)	–0.03 (–0.23 to 0.16)	–0.04 (–0.31 to 0.22)
MANSA	–0.17 (–0.37 to 0.02)	–0.23 (–0.49 to 0.03)	–0.30 (–0.65 to 0.04)

a Denotes significance at $p < 0.05$.

Subgroup analysis

Preplanned subgroup analyses were conducted in order to assess whether or not there was any difference in response between participants with high and low symptoms, and between those with a long or short duration of illness. The outcomes assessed included the PANSS negative subscale, the CAINS subscales, and the Calgary Depression Scale. The composition of the subgroups for each instrument evaluated is reported in *Table 7*, and the results of the subgroup analyses are presented in *Tables 8–10*. No significant differences in response were detected in the primary outcome between patients with higher negative symptoms at baseline (adjusted difference in means = 1.19, 95% CI –0.56 to 2.94; p for interaction = 0.184) or a longer duration of illness, both when split at 5 years of illness duration (adjusted difference in means = –1.57, 95% CI –4.09 to 0.96; $p = 0.224$) and 15 years of illness duration (adjusted difference in means = –1.28, 95% CI –3.39 to 0.83; $p = 0.234$). With regards to the CAINS subscales and Calgary Depression Scale, again no significant differences in response between the subgroups were detected.

TABLE 7 Numbers and proportions in each subgroup category for the PANSS, CAINS scale and Calgary Depression Scale

Outcome	Subgroup category	*N*	BPT, *n* (%)	Pilates, *n* (%)
PANSS negative subscale	PANSS negative < 23	129	63 (46.3)	66 (52.0)
	PANSS negative ≥ 23	134	73 (53.7)	61 (48.0)
	Illness ≤ 5 years	37	18 (15.8)	19 (18.1)
	Illness > 5 years	186	96 (84.2)	86 (81.9)
	Illness ≤ 15 years	155	79 (69.3)	76 (72.4)
	Illness > 15 years	64	35 (30.7)	29 (27.6)
CAINS experience subscale	PANSS negative < 23	129	63 (46.3)	66 (52.0)
	PANSS negative ≥ 23	134	73 (53.7)	61 (48.0)
	Illness ≤ 5 years	37	18 (15.8)	19 (18.1)
	Illness > 5 years	186	96 (84.2)	86 (81.9)
	Illness ≤ 15 years	155	79 (69.3)	76 (72.4)
	Illness > 15 years	64	35 (30.7)	29 (27.6)
CAINS expressive subscale	PANSS negative < 23	128	64 (48.1)	64 (51.2)
	PANSS negative ≥ 23	130	69 (51.9)	61 (48.8)
	Illness ≤ 5 years	36	18 (16.2)	18 (17.5)
	Illness > 5 years	178	93 (83.8)	85 (82.5)
	Illness ≤ 15 years	151	77 (69.4)	74 (71.8)
	Illness > 15 years	63	34 (30.6)	29 (28.2)
Calgary Depression Scale	PANSS negative < 23	129	63 (47.4)	66 (52.4)
	PANSS negative ≥ 23	130	70 (52.6)	60 (47.6)
	Illness ≤ 5 years	36	18 (16.2)	18 (17.3)
	Illness > 5 years	179	93 (83.8)	86 (82.7)
	Illness ≤ 15 years	151	76 (68.5)	75 (72.1)
	Illness > 15 years	64	35 (31.5)	29 (27.9)

TABLE 8 Difference in treatment response between those with high (≥ 23) and low (< 23) negative symptoms as measured with the PANSS negative subscale

Outcome	Adjusted difference in means	95% CI	*p*-value
***PANSS negative subscale* (n = *263*)**			
Treatment	–0.57	–2.00 to 0.87	0.437
Illness severity	–0.56	–2.23 to 1.11	0.510
Treatment × illness severity	1.19	–0.56 to 2.94	0.184
***CAINS experiential subscale* (n = *263*)**			
Treatment	0.05	–1.54 to 1.63	0.955
Illness severity	0.42	–1.13 to 1.97	0.592
Treatment × illness severity	–0.01	–2.16 to 2.15	0.997
***CAINS expressive subscale* (n = *258*)**			
Treatment	–0.16	–1.01 to 0.69	0.710
Illness severity	1.16	0.25 to 2.08	0.013
Treatment × illness severity	–0.89	–2.03 to 0.26	0.130
***Calgary Depression Scale* (n = *259*)**			
Treatment	–0.59	–1.60 to 0.43	0.256
Illness severity	–0.81	–1.84 to 0.22	0.123
Treatment × illness severity	1.19	–0.25 to 2.62	0.105

TABLE 9 Difference in treatment response between those with long (> 5 years) and short (≤ 5 years) illness duration

Outcome	Adjusted difference in means	95% CI	*p*-value
***PANSS negative subscale* (n = *219*)**			
Treatment	1.47	–2.00 to 0.87	0.437
Illness duration	0.79	–1.01 to 2.59	0.388
Treatment × illness duration	–1.57	–4.09 to 0.96	0.224
***CAINS experiential subscale* (n = *219*)**			
Treatment	1.01	–1.78 to 3.80	0.479
Illness duration	1.84	–0.29 to 3.97	0.090
Treatment × illness duration	–0.68	–3.73 to 2.38	0.663
***CAINS expressive subscale* (n = *214*)**			
Treatment	0.70	–0.82 to 2.22	0.367
Illness duration	1.57	0.40 to 2.76	0.009
Treatment × illness duration	–1.60	–3.23 to 0.04	0.055
***Calgary Depression Scale* (n = *215*)**			
Treatment	–0.78	–2.66 to 1.10	0.413
Illness duration	–0.08	–1.55 to 1.40	0.921
Treatment × illness duration	0.68	–1.38 to 2.74	0.517

TABLE 10 Difference in treatment response between those with long (> 15 years) and short (≤ 15 years) illness duration

Outcome	Adjusted difference in means	95% CI	*p*-value
***PANSS negative subscale* (n = *219*)**			
Treatment	0.56	–0.87 to 1.20	0.441
Illness duration	–0.24	–1.81 to 1.34	0.770
Treatment × illness duration	–1.28	–3.39 to 0.83	0.234
***CAINS experiential subscale* (n = *219*)**			
Treatment	0.18	–1.20 to 1.66	0.795
Illness duration	0.09	–1.78 to 1.96	0.923
Treatment × illness duration	0.92	–1.63 to 3.47	0.479
***CAINS expressive subscale* (n = *214*)**			
Treatment	–1.61	–1.01 to 0.67	0.710
Illness duration	0.01	–1.00 to 1.02	0.983
Treatment × illness duration	0.03	–1.34 to 1.40	0.969
***Calgary Depression Scale* (n = *215*)**			
Treatment	–0.33	–1.26 to 0.61	0.495
Illness duration	0.13	–1.13 to 1.39	0.841
Treatment × illness duration	0.32	–1.39 to 2.04	0.711

Adverse events

No serious adverse events occurred during the groups. During the follow-up phase, one participant died, but this was unrelated to the trial or the intervention they received. Throughout the implementation of the project there was no evidence of exacerbation of psychotic symptoms as a consequence of taking part in the BPT or Pilates groups.

Economic analysis

Service use

The proportion of those who used different health services, and the mean number of contacts that these participants made are presented in *Table 11*. At baseline, service use was broadly similar. Slightly more participants in the Pilates group accessed their general practitioner (GP) services (70% in comparison with 61%) and, in those who did report making contact, a slightly higher number of appointments were made in the Pilates group (mean = 2.1, SD = 1.5, in comparison with mean = 1.8, SD = 1.1). A higher proportion of participants in the Pilates group reported regular contact with a social worker (39% in comparison with 24%) and general psychiatric outpatient contacts (51% in comparison with 43%), whereas in the BPT group it was more common for participants to be in contact with a community psychiatric nurse (30% in comparison with 20%). In the 3 months prior to the baseline assessment, only two patients, both in the BPT group, reported a psychiatric inpatient admission. Almost all patients (97% of those in the Pilates group and 99% in the BPT group) reported being on at least one mental health medication. Most were prescribed antipsychotic medication, such as olanzapine (Zyprexa; Eli Lilly and Company), clozapine (Clozaril, Novartis), flupentixol (Depixol, Lundbeck Ltd) or risperdal (Risperdal, Janssen Pharmaceutica) and antidepressant drugs, such as fluoxetine (Prozac, Eli Lilly and Company), citalopram (Cipramil, Lundbeck), mirtazapine (Remeron, Merck and Company) or sertraline (Zoloft, Pfizer).

TABLE 11 Number of participants using services and their volume of use

	Baseline						End of treatment						6-month follow-up					
	BPT ($N = 138$)			Pilates ($N = 135$)			BPT ($N = 134$)			Pilates ($N = 127$)			BPT ($N = 131$)			Pilates ($N = 124$)		
Service	*n* (%)	Mean	SD	*n* (%)	Mean	SD	*n* (%)	Mean	SD	*n* (%)	Mean	SD	*n* (%)	Mean	SD	*n* (%)	Mean	SD
Number of contacts																		
General practitioner	86 (61)	1.8	1.1	95 (70)	2.1	1.5	64 (48)	1.3	0.5	60 (47)	1.6	1	65 (50)	1.6	0.9	79 (64)	1.5	0.9
Primary care nurse	36 (26)	2.2	1.7	31 (23)	2.2	2.5	34 (25)	1.3	0.6	28 (22)	1.5	0.6	24 (18)	1.8	1.3	26 (21)	1.4	0.6
Social worker	34 (24)	3.3	2	53 (39)	3.4	2.6	29 (22)	1.8	2.2	37 (29)	2.2	2.1	24 (18)	2.2	1.3	30 (24)	1.8	1.5
Community psychiatric nurse	41 (30)	4.7	3.2	27 (20)	4.6	2.2	29 (21)	2.2	2.6	24 (18)	1.6	1.1	27 (21)	2	1.7	26 (21)	1.5	0.5
Care co-ordinator	30 (22)	3.5	1.9	29 (21)	5.4	10.7	42 (31)	2.3	4.2	38 (30)	2.2	1.7	29 (22)	1	0	30 (24)	1.1	0.2
Other community service	24 (17)	10.5	16.8	27 (20)	8.7	11.5	30 (22)	5.5	7.3	27 (21)	5.5	7.7	26 (20)	4.3	4.9	24 (19)	8.6	13.4
Other inpatient	3 (2)	1	0	4 (3)	3	2.7	3 (2)	1.5	1.6	2 (2)	1.6	1.2	1 (1)	1	–	0 (0)	–	–
Psychiatric outpatient	60 (43)	1.6	1.7	69 (51)	1.4	0.9	39 (29)	1.5	1.6	42 (33)	1.6	1.2	38 (29)	1.2	0.8	37 (30)	1.5	0.9
Other outpatient	53 (38)	1.7	1.7	48 (36)	2.3	1.9	28 (15)	1.4	1	39 (31)	1.6	1.1	36 (27)	2.1	3.4	32 (26)	1.4	0.7
Number of days																		
Psychiatric inpatient	2 (1)	30.5	34.6	0 (0)	–	–	3 (2)	13.3	12	2 (2)	15.5	7.8	3 (2)	27.7	26	1 (1)	75	–
Number taking medication	139 (99)	–	–	131 (97)	–	–	133 (99)	–	–	123 (97)	–	–	130 (99)	–	–	120 (97)	–	–

At both the end of treatment and the 6-month follow-up stages, again, only minimal differences between the service use in the two conditions were apparent. A higher proportion of participants in the Pilates group reported a contact with a social worker both at the end of treatment and at the 6-month follow-up (29% in comparison with 22% at end of treatment, and 24% in comparison with 18% at 6-month follow-up) and a greater number of GP contacts at 6 months' follow-up (64% in comparison with 50%). Participants in the BPT group reported more frequent contacts with a community psychiatric nurse at the end-of-treatment stage [mean number of contacts = 2.2 (SD = 2.6) in comparison with 1.6 (SD = 1.1)] and participants in the Pilates group reported more frequent contacts with other community services at the 6-month follow-up stage [mean = 8.6 (SD = 13.4) in comparison with 4.3 (SD = 4.9)]. All other figures were broadly comparable across the two groups. In both conditions the number of psychiatric hospital admissions reported at both assessment points was very low (1–2%).

The mean service costs for participants (not including the costs of the interventions) are presented in *Table 12*. At baseline, the cost of service use was higher in the BPT group [£515 (SD = £1752) in comparison with £417 (SD = £572)]; however, this was primarily attributable to the costs of two inpatient admissions. Overall, the differences in costs at both end of treatment and at 6 months' follow-up were marginal.

The mean cost of the BPT intervention was £152 (SD = £63), while for Pilates it was £89 (SD = £60). Over the whole follow-up period, the mean costs were £2297 (SD = £2835) for BPT and £2442 (SD = £3278) for Pilates. Adjusting for baseline, BPT had mean costs that were £25 lower than for Pilates, but this was not statistically significant (95% CI, –£671 to £721). In the sensitivity analyses when the costs of Pilates were changed to zero, the BPT had costs that were on average £55 higher, which again was not statistically significant (bootstrapped 95% CI = –£630 to £706).

TABLE 12 Cost of services use (excluding intervention) prior to baseline and follow-up assessments (2013/14, £)

	Baseline				End-of-treatment follow-up				6-month follow-up			
	BPT (n = 138)		Pilates (n = 135)		BPT (n = 134)		Pilates (n = 127)		BPT (n = 131)		Pilates (n = 124)	
Services	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
General practitioner	68	105	79	95	40	60	50	88	51	87	63	77
Primary care nurse	8	26	9	28	1	5	2	7	1	7	2	10
Social worker	30	71	51	116	16	50	24	52	9	38	15	109
Community psychiatric nurse	59	138	27	70	20	70	9	26	15	47	11	27
Care co-ordinator	3	7	4	15	17	45	25	64	8	17	10	21
Other community service	33	130	49	198	17	81	17	80	15	85	21	104
Psychiatric inpatient	154	1642	0	0	103	858	85	718	221	1836	211	2351
Other inpatient	13	85	52	380	22	166	9	73	4	51	0	0
Psychiatric outpatient	77	149	78	101	48	120	59	112	38	77	47	91
Other outpatient	73	147	89	147	30	76	52	105	64	218	40	79
Total costs (£)	515	1752	417	572	314	912	334	800	428	1865	420	2367

Assessment of quality-adjusted life-years

In the BPT group, the EQ-5D-5L values were 0.74 at baseline, 0.76 at end of treatment and 0.71 at the 6-month follow-up stage. The figures for Pilates were very similar: 0.76, 0.76 and 0.72, respectively. The maximum QALY accrual was 0.69 (36 weeks divided by 52). The mean QALY accrual for the BPT group was 0.517, whereas for the Pilates group it was 0.516. The difference adjusting for baseline was 0.008 in favour of BPT; however, this difference was not significant (95% CI –0.019 to 0.035).

Cost–utility analysis

The cost–utility results are presented in *Table 13*. The base-case results of the analysis suggest that BPT has lower costs and produces more QALYs than Pilates; however, the differences in both cases were very small and non-significant. Consequently, despite BPT being found to be technically dominant, any analysis on which these estimates are based is likely to carry a substantial degree of uncertainty.

The CEP (*Figure 2*) indicates that there is a 37.9% chance that BPT is cheaper and produces more QALYs, and a 35.4% chance that BPT is more expensive and produces more QALYs. Over 1000 replications, Pilates was found to produce more QALYs in 26.7% of cases. As presented in the CEP (*Figure 3*), at £20,000 per QALY there is approximately a 65% likelihood that BPT is more cost-effective than Pilates.

Cost-effectiveness of improving negative symptoms

In comparison with the Pilates group, participants in the BPT reported a slightly larger improvement by the 6-month follow-up stage (difference in means = –1.6 in comparison with –1.4). Dividing the cost by the difference in change scores (0.21) shows that BPT has lower costs and better outcomes, making BPT the dominant option. However, difference between the groups was marginal. The ICER is £119, which is the cost incurred by BPT to produce an extra unit improvement on this scale. As presented in the CEP (*Figure 4*), there was a 33.5% chance that BPT was dominant (i.e. less costly and more effective) compared with Pilates. The north-east quadrant, defining a scenario of BPT having higher costs and better outcomes, has a 33.1% proportion of ICERs, whereas the south-west quadrant indicating lower costs and worse outcome, is represented by the lower proportion of bootstrapped ICERs.

TABLE 13 Differences in incremental costs, effects and cost-effectiveness at 6 months' follow-up

Cost of outcome category	BPT ($n = 140$)	Pilates ($n = 135$)	Incremental difference (adjusted)	95% CI of difference
Health and social care costs, £ (mean)	2297	2442	145 (25)	–671 to 721
QALY (EQ-5D)	0.517	0.516	0.001 (0.008)	–0.019 to 0.035
Incremental cost-effectiveness	Dominant	Dominated		
PANSS negative score	21.8	21.5	0.3 (0.21)	
Incremental cost-effectiveness	Dominant	Dominated		

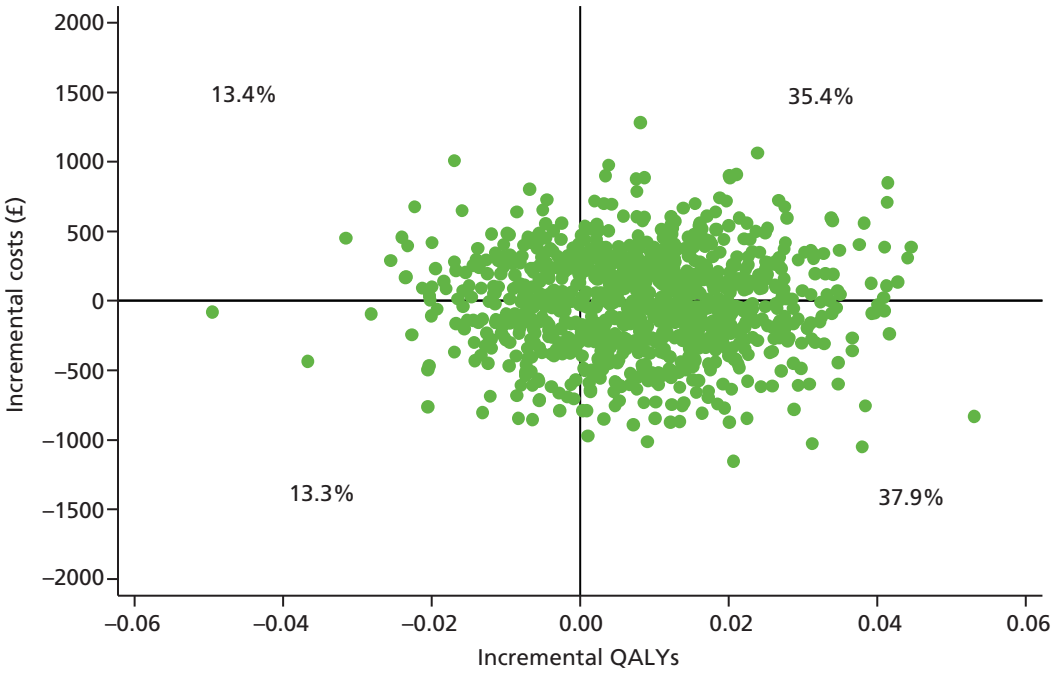

FIGURE 2 Cost-effectiveness plane of 1000 bootstrap-replicated ICERs for BPT compared with Pilates, based on health and social care costs and QALYs over 6 months, adjusted for baseline costs and utility.

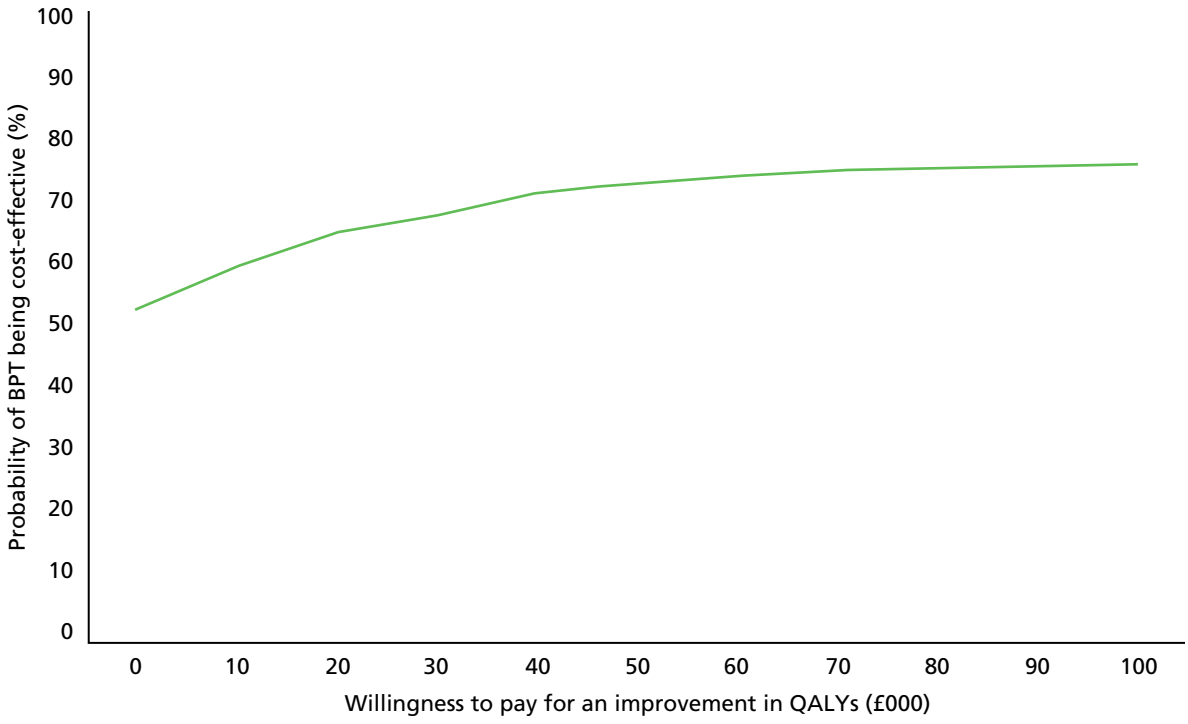

FIGURE 3 Cost-effectiveness acceptability curve indicating the probability that BPT is cost-effective compared with Pilates, base on health and social care costs and QALYs over 6 months.

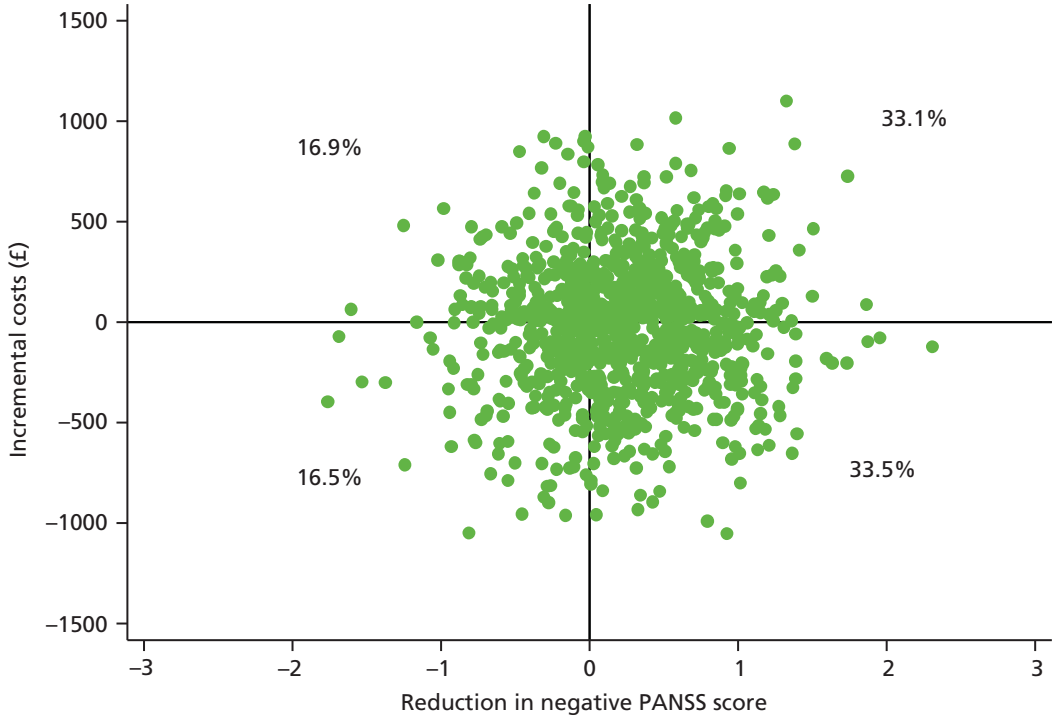

FIGURE 4 Cost-effectiveness plane of 1000 bootstrap-replicated ICERs for BPT compared with Pilates, based on health and social care costs and negative symptom change over 6 months, adjusted for baseline costs and PANSS negative subscale score.

Chapter 4 Discussion

Study findings

In a study of 275 participants, no significant differences between BPT and Pilates were detected in the PANSS negative symptoms subscale, either at the end of treatment or 6 months later. In the secondary outcomes at the end of treatment, significant differences were detected in the CAINS expression subscale and the extrapyramidal symptoms, both in favour of BPT. However, these differences are unlikely to be of a sufficient size to represent a clinically meaningful benefit. At the 6-month follow-up stage, there was no longer a significant difference in the CAINS expression subscale. However, a difference in extrapyramidal symptoms was still present. These findings were consistent in the sensitivity analysis that was completed on imputed data sets, and in the CACE analysis, in which those who attended at least 5 and 10 sessions of BPT were defined as treatment compliers. No significant differences in outcome were detected between those with high and low symptom scores, or with a long and short duration of illness. In the economic analysis, no significant differences were found in service use or QALYS at the follow-up stage. In the cost-effectiveness analysis, the results were marginally in favour of BPT. However, there was substantial uncertainty in the estimates. Overall, there was no evidence that BPT is an effective treatment for patients with negative symptoms of schizophrenia as compared with Pilates as an active control.

Interpretation

The study retention rates from randomisation to the 6-month follow-up were high. Over 90% of participants remained in the study at 6 months' follow-up, which was a far higher figure than anticipated. The large sample size and minimal dropout meant that the study was highly powered (> 94%) to detect a clinically important difference in the primary outcome. The inter-rater reliability for the PANSS was high (PANSS ICC = 0.85), with no evidence of rater drift as the trial progressed. The BPT intervention was manualised, and therapists were largely adherent to treatment, suggesting that the intervention had been delivered as originally intended. Approximately 35% of participants who were approached declined to take part in the study, which may appear quite high, but this was not unexpected, given that the physically active nature of the groups and the fact many patients typically experienced prominent symptoms of amotivation and asociality. With regard to those who did agree to take part, participants in the BPT group attended a median of 11 sessions [interquartile range (IQR) = 5–17], whereas those randomised to the Pilates group attended eight sessions (IQR = 1–15). Approximately 40% of participants randomised to the BPT condition attended at least three-quarters of the sessions offered. This could be considered relatively high and compares favourably with a similar trial in art therapy on this patient sample.[8] In this study,[8] participants typically reported a long duration of illness (median 11 years, IQR = 7–18), with multiple hospital admissions (median 3, IQR = 1–5) and moderate negative symptoms (PANSS negative 23.2, SD = 4.3). Overall, the participant characteristics of the sample should be considered to be both representative of the schizophrenia population in secondary care in the UK and the types of patients who would be considered appropriate for focused treatments for negative symptoms. Finally, given that the intervention evaluated is not dependent on any particular health-care system, these findings should be considered to be relevant to all countries that might consider using art therapies as a treatment for negative symptoms of schizophrenia.

One important limitation of the study is that, given the absence of any treatment-as-usual control group, this study is unable to discount the possibility that BPT and Pilates may be equally effective in reducing symptoms. If, indeed, this is the case then this reduction could either be attributable to the non-specific effects of both groups, such as the provision of structured group activity and therapist attention, or overlapping specific therapeutic factors, albeit delivered in different forms. In Pilates, the focusing on bodily experiences on a cognitive and emotional level may not be explicit in a similar manner to that of BPT. However, Pilates exercises that emphasise centring, concentration and a focus on breathing may foster such links in a more subtle, implicit way. In support of this, the link between movement-based exercises, such as Pilates and mindfulness, have been increasingly emphasised,[29,30] which is important, given that there is some evidence to suggest that mindfulness might help reduce negative symptoms.[31] Furthermore, although the facilitation of emotional group interactions in the Pilates groups was discouraged, observations from the videotapes of the groups suggest that this did occur on occasions (particularly at the beginning and end of groups), suggesting at least some degree of contamination may have occurred.

Although it is possible that both of the groups may have had an effect on negative symptoms, this appears to be unlikely. The within-group reductions in both groups appear to be relatively small, with only a 1.5-point reduction in the PANSS negative subscale in both the BPT and Pilates groups, which is half of the change used to determine a clinically meaningful difference in the sample size calculation. In addition, although it is impossible to determine what the change over time would have been in a control arm from the same population investigated here, in a recent meta-analysis looking at the change in negative symptoms over time in schizophrenia outpatients this reduction appears comparable with placebo/treatment-as-usual conditions,[61] suggesting that the groups provided little additional benefit. Given that the symptom change in the Pilates group was similar to control conditions from other studies, it suggests that adopting Pilates as a comparator was appropriate, with the findings generalisable to other active controls, presuming that they do not provide any additional clinical benefit over treatment as usual either.

Another possible limitation is that, being only 20 sessions long, the treatment under investigation was relatively short, given the population recruited. The participants were typically stable, highly chronic in nature and had experienced multiple hospital admissions over the course of their illness, so it may be somewhat ambitious to expect substantial, lasting changes over only a 10-week treatment. In support of this, a meta-analysis looking at a different form of arts therapy – namely music therapy – suggested that > 40 sessions were required before large effect sizes could be detected in the treatment of negative symptoms.[32] However, the same meta-analysis also found that a small effect could be expected in as few as three sessions, whereas in this study the CACE analysis did not detect a significant improvement in those who attended at least five sessions and 10 sessions, respectively. Therefore, although it remains unclear whether or not more prolonged exposure to the therapy would result in clinically significant changes to negative symptoms, the lack of any effect at all in participants who did comply with treatment suggests that this may be unlikely.

In this study, participants who were randomised to the BPT group attended significantly more sessions than those who were randomised to the Pilates group. The reasons for this are not entirely clear. One possible reason could be that, as experienced clinicians, the body psychotherapists were likely to have a lot more experience at engaging people with severe mental health problems. A second possibility might be that given the BPT treatment administered was designed specifically for this clinical population, it may have been easier for the participants to engage in and more appropriate to their capabilities. In support of this, despite the Pilates group being run at a beginner's level, some participants did report having difficulty in conducting the exercises, and particularly when attendance was sporadic. A third possibility might be related to participant treatment expectation, with people more motivated to take part in a 'therapy' as opposed to a 'control' arm. Finally, higher attendance may have related to patient preference, with patients actually preferring BPT, even if it did not appear to result in significantly improved outcomes over the Pilates.

Generalisability

The findings from this study are in contrast with those in the explanatory trial that was included in the NICE review of arts therapies.[6,17] In that small-scale exploratory study,[6] a significant reduction in negative symptoms was found in the BPT group in comparison with a supportive counselling control group. One possible reason for the difference could be that In the exploratory trial the minimum level of negative symptoms as an inclusion criteria was set higher (at least 21 on the PANSS negative subscale in comparison with at least 18 in the present study). However, no significant difference in treatment response was detected in the subgroup analysis that compared participants with PANSS negative scores above and below a score of 23 at baseline. Another possible explanation for the difference between the findings is that in the exploratory trial there was no active control, so effects could be attributable to the non-specific effects of structured group activity. However, the within-group changes in this study do not support this given they were more comparable with that found in the supportive counselling group of the exploratory trial (difference in means = –1.3) as opposed to the BPT group (difference in means = –4.5). One other possible explanation is the less rigorous blinding in the exploratory trial. It was estimated they could have been unblinded on as many as 50% of occasions at the end-of-treatment stage, and there were insufficient personnel for a different assessor at the follow-up stage when unblinding did occur. In the present study, blinding was maintained up until the primary outcome in 94% of cases, and in the event of an assessor becoming unblinded, efforts were made for a different researcher to conduct the follow-up assessment. Consequently, it is quite possible that the assessor expectations of improvement in the exploratory trial may have led to bias in the rating values.

The findings of this study also appear to contrast with earlier investigations into body-orientated treatments for negative symptoms.[20–22] However, all of these investigations appear to have serious methodological shortcomings. In the Darby study,[21] for example, only 15 participants were recruited in each intervention arm; the interventions themselves consisted of only one session, lasting approximately 15 minutes in total; the participants' perceptions of the body were using a Holtzman Inkblot Test,[62] as opposed to any standardised measure of negative symptoms, and differences in pre–post scores immediately before and after the intervention were evaluated, rather than comparing the effectiveness directly with a control condition. In the Nitsun *et al*. study,[22] only 12 participants were recruited into the control and experimental arms; analysis was conducted within groups, rather than between groups; functioning and body image were assessed using non-standardised methods, such as the Rorschach test[63] and an unpublished draw-a-person body image scale; and it is unclear whether or not the improvements detected were a consequence of the non-specific effects of increased therapist attention (particularly given the large number of therapists and cofacilitators that both the treatment and control interventions adopted). In the Goertzel *et al.* study,[20] although the sample size was larger than the other trials, there were significant issues with regards to symptoms assessment and statistical analysis. Improvements were measured by unstandardised reports of psychiatrists (who were blinded) and nurses (who were not blinded) at the end of treatment only. Given that the baseline measures were not conducted, it is unclear whether or not any differences between the groups may be attributable to patients being different at study entry (particularly given that the details of the randomisation procedure are not provided). In addition, although significant differences were detected in four different areas (overall improvement, affective contact, mobility and general functioning), in 17 other measures no significant differences were detected and no primary outcome was prespecified, which leads to the possibility that any differences detected may be attributable to chance findings from multiple testing. Lastly, in a study by Andres *et al.*,[64] only 10 participants were recruited, there was no comparator, and only physiological measurements and participants' self-perceptions were assessed. These would not necessarily be indicative of negative symptoms, and are likely to be influenced by regression to the mean. Overall, although there are some historical findings that contradict the findings of this study and support the use of body psychotherapeutic techniques in the treatment of schizophrenia, considerable caution would be recommended in interpreting these study findings.

The findings of this study mirror those reported in the MATISSE trial,[8] which evaluated conventional art therapy, rather than BPT. However, in the NICE guideline arts therapies review,[6] no such distinction is made between modalities. The positive results in studies in that review, which included small-scale studies both on BPT[12] and art therapy,[37,38] have not been replicated in either the present trial or in the MATISSE study,[8] which were both much larger. Therefore, although the findings of this study and the MATISSE study[8] do not necessarily preclude the possibility that different types of arts therapies (such as music therapy) may still be effective, they are not consistent with the current NICE recommendation that all types of arts therapies should be considered as a treatment for negative symptoms or schizophrenia, and, furthermore, do not support the evidence on which the NICE recommendation was initially based.

The MATISSE trial[8] followed a highly pragmatic design, aiming to evaluate art therapy as it is delivered in routine practice in the UK. Although providing a close approximation of what could be delivered in 'the real world', the study[7] was criticised for a lack of clarity of the model of treatment being evaluated[8,9] (although this critique has since been disputed).[11] In the trial that we conducted, the mechanism of action and model of implementation were clearly defined in a treatment manual designed prior to the study taking place, and adherence to the method was assessed to ensure that the treatment was appropriately delivered. Although this offers a significant advantage over the more pragmatic design that was delivered in the MATISSE study,[8] this does also have a number of limitations. First, it can be disputed that the intervention that we assessed may deviate from current routine practice, weakening the generalisability of the results, and, second, given that the intervention delivered by the therapists may deviate from typical practice, this may result in a performance bias. With regard to the second point, there is some evidence to suggest the effectiveness of a complex intervention increases as the therapists become more experienced in implementing the therapy in a research context, given that it may differ from their usual practice and require different competencies.[65] In this study, the body psychotherapists were typically highly experienced in working with this clinical population; however, conducting a maximum of only two groups may have meant that there was insufficient time for therapists to gain experience of working within the confines of a clinical trial. Given the different strengths and weaknesses of the methodologies used by both this study and the MATISSE trial,[8] the consistency of the findings between the two trials add considerable weight to the conclusion that arts therapies, as they are currently defined, should not be considered an effective treatment for negative symptoms of schizophrenia.

In the secondary outcomes, a small significant improvement in the BPT group was detected in expressive symptoms, as measured by the CAINS at end of treatment, and in movement disorder symptoms both at the end of treatment and at 6 months' follow-up. For both findings it is important to consider that multiple testing was conducted, and therefore these observed differences may be attributable to an inflated type 1 error. To date, no studies have evaluated to what extent improvements in the CAINS subscales equate into clinically meaningful benefits, unlike with the PANSS.[39] However, the only marginal difference detected between the groups in the CAINS experiential subscale suggests that the improvements are unlikely to translate into a clinically meaningful change. In any case, the significant difference was not maintained 6 months later. Regarding the change in movement disorder symptoms detected, given that a number of items from the SAS scale could not be scored during the assessments, one should, again, be somewhat cautious in how these findings are interpreted. Although it is intuitive to consider that a treatment focusing specifically on the body may help alleviate movement-related symptoms, it would be advisable to re-examine this finding, using a fully validated scale to measure such symptoms, before any firm conclusions can be drawn.

Overall, this study does not support group BPT as a treatment for negative symptoms of schizophrenia. In conjunction with the MATISSE trial,[8] these findings are not consistent with the NICE recommendations[6] for arts therapies as a treatment for negative symptoms of schizophrenia. However, patients with severe negative symptoms showed relatively good attendance in both group conditions and follow-up rates were very high. This suggests that it is possible to implement rigorous trials with this challenging patient group, and that the format might be appealing. Future research could build on this promising experience, even if the specific methods of interventions will have to be different.

Chapter 5 Conclusions

Implications for health care

In comparison with an active control, group BPT does not have a clinically relevant beneficial effect in the treatment of patients with negative symptoms of schizophrenia. BPT was not found to result in clinically meaningful benefits over and above an active control, and no significant difference was detected in either outcomes or costs in the cost-effectiveness analysis.

These findings are not consistent with the current NICE guidelines,[6] which suggest that art therapies may be an effective treatment for negative symptoms. In conjunction with the recent findings of the MATISSE trial,[8] our findings suggest that these recommendations may require amending. At this stage we are unable to determine whether arts therapies, as a whole, are not effective for this patient group or it is just that BPT and art therapy, specifically, are not effective. This being the case, it is still not clear whether the recommendation of arts therapies for this patient group should be withdrawn or amended so that the individual types of arts therapies are separately evaluated.

Whereas no improvements in the primary outcome was detected in those who were randomised to the BPT group, significant improvements in movement disorder-related symptoms were detected, and these improvements were maintained 6 months later. Although caution should be advised in interpreting this result, given the fact that the SAS used was not fully administered, improvements in this area were not anticipated beforehand and patients were not recruited with this particular issue in mind, it does suggest that body-orientated therapies may be a possible avenue to treat movement-related symptoms.

Despite the BPT and Pilates groups not appearing to provide any clinically meaning benefit, the relatively high attendance in both arms was notable, given that this patient group reported moderate levels of anhedonia, avolition and asociality. In addition, in both groups, participants reported a high level of treatment satisfaction when assessed at the end of treatment. These results suggest that even if these active interventions do not have a direct impact on negative symptoms, organised, regular group activity can be attractive to this patient group. Offering such groups may be a way to decrease social isolation and increase physical activity levels, which is important, given the associated physical health benefits.[36] In addition, the high participant attendance shows that trials evaluating such interventions can be successfully implemented in the community.

Recommendations for research

1. An update of the NICE review[6] examining the effectiveness of arts therapies as a treatment of negative symptoms of schizophrenia may be required, following the results of both this study and the MATISSE study.[8] These two studies include significantly more participants than all of the studies currently included in the review combined ($n = 692$ compared with $n = 382$). Including a network meta-analysis comparing the effectiveness of different art therapy types may be especially informative.
2. Evaluate the effectiveness of BPT as a treatment for negative symptoms over a greater number of sessions. Other psychosocial treatments for schizophrenia, such as cognitive rehabilitation therapy, are typically administered over 40 sessions,[66] so it is feasible that more sessions may be required for BPT to be effective.
3. Conduct a full-scale RCT examining the effectiveness of music therapy as a treatment for negative symptoms of schizophrenia to help determine whether or not treatment outcomes are different between different art therapy types.
4. Evaluate the possibility of BPT as a treatment of EPSs resulting from medication side effects, following the significant improvements detected in the SAS.

Other information

Protocol

The protocol for the study was published in the open access journal *BMC Psychiatry* (www.biomedcentral.com/1471–244X/13/26).

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Contributions of authors

Stefan Priebe was the chief investigator for the project and was involved in all aspects of the design, management and study implementation. Stefan Priebe is also the guarantor for the study.

Mark Savill was the trial manager for the project and was involved in the study design and implementation.

Til Wykes was a principal investigator on the project and was involved in study design and study management, in addition to implementation in her respective study sites.

Richard Bentall was a principal investigator on the project and was involved in study design and study management, in addition to implementation in his respective study sites.

Christoph Lauber was a principal investigator on the project and was involved in study design and study management, in addition to implementation in his respective study sites.

Ulrich Reininghaus was a principal investigator on the project and was involved in study design and study management, in addition to implementation in his respective study sites.

Paul McCrone was the chief health economist and was involved in the study design and managing the economic evaluation.

Iris Mosweu was the health economist on the project and completed the economic evaluation.

Stephen Bremner was the trial statistician, writing the statistical analysis plan and conducting the analysis.

Sandra Eldridge was the chief statistician and was involved in study design, providing oversight for all aspects of the design and analysis, including the randomisation and analysis plan.

Frank Röhricht was a consultant on the project and was involved the study design, ongoing study management and the implementation of the therapeutic interventions.

All authors were involved in the preparation of this manuscript.

Data sharing statement

Anonymised data are available from the corresponding author on reasonable request and are subject to a Data Sharing Agreement.

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Appendix 1 Body psychotherapy session sheet

Body Oriented Psychotherapy Record Form

Date:_____Session Number:____ Therapist:_____

Events in each of 5 part session:

1._Opening Circle	
2._Warm up:	
3._Structured tasks:	
4._ Creative Play:	
5_Closing circle:	

Participant process observation (specific features)

Ini-tials	Body related subjective experiences	Body related objective observations	Movement, gestures & emotional expression

Group process observations:

General Evaluation: **Including energy levels (high, normal, low) , group process/dynamics (e.g. splitting, fragmented, confrontational, withdrawn, unified, challenging), overall feeling of how session progressed, level of openness/cooperation in patients, level of trust, and any other subtle features/shifts, level of engagement**	
Predominant Body experiences (subjectively reported and objectively observed)	
Predominant Movement themes **Predominant efforts**: **Use of space**:	
Predominant Psychological themes: **What themes are evoked, e.g. dependency, withdrawal, destructiveness, enthusiasm, compliance, passivity etc**	
Interrelational: **Transference and counter-transference feelings**	

Plan for following session: (Events related to 5 parts):

1.

2.

3.

4.

5.

Appendix 2 Body Psychotherapy Adherence Scale

Body Psychotherapy Adherence Scale (BPT-AS)

The BPT-AS is composed of 10 items and has been developed in order to test adherence to protocol and treatment distinctiveness. Each of the 10 items is rated on a 0 to 2 point scale (0 = no evidence, 1= limited evidence, 2=definite evidence).

Most BPT-AS items assess therapist behaviours specific to BPT in chronic schizophrenia (BPT-CS), e.g. movement interventions, bodily self-awareness exercises; the first three items relate to aspects of the therapy practice that BPT shares with other group therapies (e.g. group cohesion, therapeutic environment, provision of therapy rationale, conveying core themes).

(Please circle each score as appropriate)

1. THERAPEUTIC ENVIRONMENT

Is there evidence that the therapist has created an appropriate therapeutic environment that enables a positive therapeutic relationship/alliance?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

2. GROUP COHESION:

Is there evidence that therapist's actions facilitate the cohesiveness and shared identity of the treatment group?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

3. PROVISION OF BPT RATIONALE:

Does the therapist provide patients with an explanation for why the performance of specific BPT tasks/interventions will help them to address specific symptoms of their illness?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

4. PROGRESSING THERAPY THROUGH FIVE SECTIONS:

Is the therapist following the 5-section structure format of the session?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

5. EXTENDED BODY-SELF-AWARENESS EXERCISES/INTERVENTIONS:

To what extent does the therapist use self-awareness exercises (e.g. body check-in/ body exploration)?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

6. MOVEMENT-BASED SELF-EXPRESSION EXERCISES/INTERVENTIONS:

To what extent does the therapist use movement exercises to foster self-expression and/or express and communicate emotions?

0 =No Evidence **1 = limited evidence** **2 = clear evidence.**

7. MOVEMENT BASED SOCIAL INTERACTION EXERCISES:

To what extent does the therapist use movement exercises to encourage social interaction?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

8. USE OF TOOLS / OBJECTS IN THERAPY:

To what extent does the therapist use a range of different tools/objects in therapy?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

9. CONSISTENCY OF PRACTICE REVIEW:

Does the therapist appropriately review the session at the end of the group?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

10. BODILY COPING STRATEGIES IN RELATION TO SPECIFIC NEGATIVE SYMPTOMS:

Does the therapist introduce and/or relate to different body based coping strategies for responding to negative symptoms?

0 =No Evidence **1 = limited evidence** **2 = clear evidence**

Any observations, comments or reflections:

Appendix 3 Pilates guide

Information for all Pilates instructors on the 'NESS' trial

The programme overleaf has been devised by Pilates instructors already involved in the Research Trial. Although it might sound quite rigid, we are happy for there to be a degree of flexibility at the discretion of each instructor, so adding an increase in the number of exercises earlier if group is advancing quickly, or increasing the warm up if clients are struggling to get a handle on correct breathing at the beginning, etc. is entirely appropriate. The intention behind devising this is not to sound too prescriptive, but to ensure that what is being delivered is consistent between instructors, and universally recognisable as a Pilates class.

With this being a research trial, the most important consideration for us is that what is being delivered is a 'pure' Pilates class, meaning additional psychotherapeutic or mindfulness/yoga techniques are not incorporated into the sessions. The reason behind this is because if any improvement in outcomes in the Pilates is detected, it will be impossible to identify whether this is attributable to the Pilates groups themselves or the additional therapeutic input provided. We would encourage all instructors and cofacilitators to be warm and polite to all participants; however any additional support, guidance or counselling to the participants should be avoided. All participants are receiving ongoing care in NHS services, so the participants will be in continual contact with trained professionals to provide any additional help they should need.

What is the purpose of the trial?

The purpose of the study is to examine the effectiveness of a manualised form of group body psychotherapy, specifically designed to reduce the negative symptoms of schizophrenia. The treatment has been found to be effective in comparison with supportive counselling in an earlier, small-scale study; however, it is currently unclear whether this is down to the psychotherapeutic component of the treatment or the structured physical activity delivered in a group setting. By comparing the effects of the treatment to a similarly structured Pilates group, we can examine whether the psychotherapeutic component is causing any additional reduction in negative symptoms over and above what we might expect from structured group activity.

What is schizophrenia, and what are negative symptoms?

Schizophrenia is a chronic, disabling condition effecting approximately 1% of the population. The symptoms of schizophrenia fall into three broad categories: **positive symptoms**, which can include hallucinations, unusual or bizarre beliefs, and unusual ways of thinking; **cognitive symptoms**, which can include an inability to understand or make use of information, attention deficits and memory problems; and **negative symptoms,** which can include flat affect, an inability to experience pleasure, reduced motivation and social withdrawal. Antipsychotic medication has been found to be effective in treating positive symptoms; however, the negative and cognitive symptoms are much more resistant to medication, hence the need to explore alternative therapies.

What is a Randomised Controlled Trial (RCT)?

A RCT is a type of experiment most commonly used to test the safety or effectiveness of an intervention in health care. Once a participant has been successfully recruited, but before the treatment begins, they are randomised into one of the treatment arms, and at the end the outcomes are compared. In this study, once 16 participants are recruited, 8 will be randomly assigned into the body psychotherapy group, and 8 in the Pilates class. Assessments will occur before treatment, after treatment and at 6 months' follow-up, with the outcomes then compared to each other.

Who is 'blinded', and what is it?

The Research Assistants (RAs), who recruit the participants and conduct the assessments will be blinded to the intervention allocation, which means they will not know whether the participant attends the Pilates or body psychotherapy group. The reason this is done is to try and minimise any effect of the RAs expectations on how effective an intervention is, which can unduly influence the assessment of how effective an intervention is. In drug trials it is usually the case for participants to also be blind to their allocation for the same reason; however, given they will be taking an active part in the trial this will obviously not be possible in this situation. The Trial Manager will not be blind to the allocation, as he will not be doing any assessments, so if you need to talk to the research team about a participant you should contact him.

What risks can we anticipate in the study?

We anticipate minimal risks to both instructors and participants in this study. All patients will be outpatients receiving ongoing care in NHS services, and deemed sufficiently stable to take part by their key worker and the research team after a risk assessment. As with any physical activity, there is a small chance of contracting injuries; however, there is a wide consensus that the benefits of physical activity overall outweigh such risks. Any participants not able undertake light physical activities will be ineligible to take part in the study.

What do I do if any adverse events/serious adverse events (AEs/SAEs) occur?

If any adverse events either occur or are identified during the course of the group, it is the responsibility of the instructor to notify the Trial Manager by telephone (see number below). In the case of any serious adverse events (SAEs) please do not hesitate to contact the emergency services as appropriate.

Who are the cofacilitators and what is their role?

The cofacilitators are volunteers who have agreed to assist both in delivering the class, and in performing some of the more practical elements involved in running the groups, such as setting up the video cameras and contacting non-attendees. The volunteers will not be qualified Pilates instructors, and so will not take any part in leading the group. In the majority of cases the volunteers will either be psychology graduates/undergraduates, and/or have some experience of working with mental health populations. As with the instructors, it is important that no volunteers provide additional psychotherapeutic input.

If you need to discuss the Trial with any member of the research team please contact the Trial Manager on **[XXXX]**.

The NEgative Symptoms of Schizophrenia (NESS) 20-session Pilates programme:

- The group is to be delivered twice a week over a period of 20 weeks, with each session lasting 90 minutes.
- The agreement was to initially start with 25- to 30-minute warm-up sessions, followed by ≈6 exercises from the list, appropriate to level.
- As the class progresses, gradually reduce the duration of the warm-up period to nearer 15–20 minutes by the 20th session in order to include more exercises. The exercises listed below are not in any set order, and have only been included as a guide. Some may be too advanced for this client group, whilst there may be other exercises not listed which are more appropriate.
- At approximately eight sessions, begin to add ≈2 exercises every four sessions, up to a total of around 12 exercises by session 16.

Warm-up

Breathing.

Imprinting.

Hip release.

Supine spinal rotation.

Cat stretch.

Hip rolls.

Scapula isolation.

Arms circle.

Head nods.

Elevation and depression of scapulae.

Exercise list

Ab prep.

Breast stroke preps 123.

Shell stretch.

Hundred.

Half roll back.

Roll up.

One leg circle.

Spine twist.

Rolling like a ball.

Single leg stretch.

Obliques.

Scissors.

Shoulders bridge prep.

Breast stroke.

Shell stretch.

Neck pull prep.

Obliques roll back

Side kick side leg-lift series 12345.

Spine stretch forward.

Single leg extension.

Swan dive prep.

Swimming prep.

Leg pull front prep.

Seal.

Side bend prep.

Push up prep.

Double leg stretches.

Appendix 4 Client report file

PANSS – Re-ordered (includes sample prompts)

a) Patient ID ⌊ ⌋⌊ ⌋⌊ ⌋ **c) Baseline/ EOT/Follow-up** (circle)

b) Assessors signature: **d) Date** ⌊ ⌋⌊ ⌋⌊ ⌋⌊ ⌋⌊ ⌋⌊ ⌋

☐ **G1** **Somatic concern** (physical complaints/beliefs about bodily illness or malfunctions)

- **How has your physical health been in the last week?**
- **Do you ever worry that you have something wrong with your body?**
- **Do you have a physical illness or disease?**
- Does your head or body ever feel strange?
- Or do you have a problem with the way your body has been functioning?
- Has your head or body changed in shape or size?

If answer is YES to any of the above:

- How serious is the problem?
- What is causing the problem?

1	The definition doesn't apply
2	Questionable pathology – patient may be upper extreme of normal limits
3	Distinctly concerned about health or somatic issues, evidenced by occasional questions or desire for reassurance
4	Complains about poor health/body malfunction, but no delusional conviction, and over-concern can be allayed by reassurance.
5	Patient expresses numerous or frequent complaints about physical illness or bodily malfunction, or reveals 1 or 2 clear cut delusions involving these themes, but is not preoccupied by them.
6	Patient is preoccupied by one or a few clear-cut delusions about physical or organic malfunction, but affect is not fully immersed in these themes, and thoughts can be diverted by the interviewer with some effort.
7	Numerous and frequently reporting somatic delusions, or a few with catastrophic nature. Which dominate affect and thinking.

G2 **Anxiety** (experiences of nervousness, worry, apprehension, or restlessness)

- **Do you find that you worry about things a lot?**
- **Have you been feeling nervous/tense/afraid within the last week?**
  If YES,

- How anxious have you been feeling on a scale of 1 to 10, with 10 being the most anxious you could ever feel?

If answer is YES to any of the above:

- Are you afraid of something/or someone?
- Do you ever get into a state of panic? Or feel shaky/faint/sweaty as a result of feeling anxious?
  - ***Definition of panic attack*** = *a feeling of intense fear and anxiety which usually comes on quite suddenly and lasts for a brief amount of time. During an attack, people usually have unpleasant bodily sensations such as: rapid heart beat, breathing very fast, feeling short of breath, chest pains, feeling faint or dizzy, trembling and sweating.*
- Have your worries or nervousness affected your appetite/sleep/ability to work in the last week?

1	The definition doesn't apply
2	Questionable pathology – patient may be upper extreme of normal limits
3	Some worry, over-concern or subjective restlessness, but no somatic/behavioural consequences are reported or evident
4	Patient reports distinct symptoms of nervousness, reflected in mild physical manifestations (e.g. fine hand tremors/perspiration)
5	Serious anxiety problems which have significant physical/behavioural consequences (e.g. marked tension, poor concentration, palpitations, impaired sleep)
6	Almost constant fear associated with phobias, marked restlessness or numerous somatic manifestations
7	Life seriously disrupted by anxiety which is present almost constantly, and at times reaches panic proportion or is manifested in actual panic attacks.

G3 **Guilt feelings** (self-blame for real or imagined misdeeds in the past)

- **Do you tend to blame yourself for things that have happened?**
- **Do you feel guilty about something you may have done in the past?**
- **Do you ever feel like you deserve punishment for something you have done?**

If YES,

- What kind of punishment do you deserve?
- What do you deserve punishment for? Is there a particular incident you have in mind?
- Have you had thoughts of harming yourself as one kind of punishment? Have you ever acted on those thoughts?

1	The definition doesn't apply
2	Questionable – patient may be upper extreme of normal limits
3	Questioning elicits a vague sense of guilt/self blame for a minor incident, but is clearly not overly concerned
4	Expresses distinct concern over responsibility for a real incident but is not preoccupied by it, and attitude/behaviour are essentially unaffected.
5	Patient expresses strong sense of guilt associated with self-deprecation or the belied that he/she deserves punishment. The guilt feelings may have a delusional basis and may be volunteered spontaneously, may be a source of pre-occupation and or depressed mood, and cannot be allayed readily by the interviewer.
6	Strong ideas of guilt that take on delusional quality – lead to hopelessness and worthlessness. Patient believes he/she deserves harsh sanctions for the misdeeds, and may regard his/her current life situation as such punishment.
7	Patients life dominated by unstable delusions of guilt, for which he/she feels deserving of drastic punishment (e.g. imprisonment, torture, death). There may be associated suicidal thoughts or attribution of others' problems to one's own past misdeeds.

G6 **Depression** (feelings of sadness, discouragement, helplessness and pessimism)

- **What has your typical mood been like in the last week?**
- **Are you mostly happy or sad?**
- **Have you had periods of feeling sad and hopeless in the last week?**

If patient is mostly sad:

- How unhappy have you been feeling on a scale of 1 to 10, with 10 being the most unhappy you could feel?
- When do you feel the saddest? How long do these feelings last?
- Do you sometimes cry? How often?
- Has your low mood affected your appetite/sleep/ability to work?
- Do you have less or nearly no interest that you used to in your leisure/social activities or hobbies or things you used to enjoy?
- Have you had thoughts of harming yourself?

1	The definition doesn't apply
2	Questionable pathology – patient may be upper extreme of normal limits
3	Expresses some sadness or discouragement only on questioning, but there is no evidence of depression in general

	attitude of demeanour.
4	Distinct feelings of sadness/hopelessness, which may be spontaneously divulged, but depressed mood minimally affects behaviour/social functioning. Can usually be cheered up.
5	Distinct depressed mood associated with obvious sadness, pessimism, loss of social interest, psychomotor retardation, and some interference in appetite or sleep. Patient cannot easily be cheered up.
6	Markedly depressed mood, misery, hopelessness, worthlessness, occasional crying. Major interference with appetite and/or sleep as well as normal motor and social functions. Signs of possible self-neglect.
7	Depressive feelings seriously interfere in most major functions. Frequent crying, pronounced somatic symptoms, impaired concentration, self neglect, social disinterest, possible depressive or nihilistic delusions. Possible suicidal thoughts/actions.

G12 life term **Lack of judgement and insight** (impaired awareness/understanding of one's psychiatric condition and situation. Denial of the need for treatment, inability to recognise psychiatric symptoms, unrealistic short- and long-term planning)

- **Do you generally feel that you are in need of help and treatment from people such as Dr XXX *(patients doctor)***
- **Do you feel you have a psychiatric illness or do you feel you have had one in the past?**

If YES

- What is it?
- How serious do you feel it is on a scale of 1 to 10 (10 being the most serious it could be)
- **Where do you see yourself/what would you hope to be doing in 1 years time/5 years time?**

1	The definition doesn't apply
2	Questionable pathology – patient may be upper extreme of normal limits
3	Recognises psychiatric disorder but underestimates seriousness, implications for treatment or the importance of taking measures to avoid relapse. Future planning may be poorly conceived
4	Vague/shallow recognition of illness. Fluctuations in acknowledgement of being ill or little awareness of major symptoms that are present such as delusions, disorganised thinking, suspiciousness and social withdrawal. May rationalise treatment to relieve lesser symptoms e.g. anxiety, poor sleep etc.
5	Acknowledge past but not present disorder. If challenged, may concede the presence of some unrelated or insignificant symptoms which tend to be explained away by gross misinterpretation or delusional thinking. Need for treatment us unrecognised.
6	Denies ever having a psychiatric disorder, Patient disavows the presence of any psychiatric symptoms in the past or present, and denies the need for treatment/hospitalisation.
7	Emphatic denial of past and present illness with current hospitalisation/treatment given a delusional interpretation (eg. As a punishment for misdeeds, or persecution by tormentors) The patient may refuse to cooperate with therapists, medication or other aspects of treatment.

P1 **Delusions** (beliefs that are unfounded, unrealistic, and idiosyncratic/peculiar)

Delusions of reference

- **Do you feel at times that others make references or say things with a double meaning?**
- **Do you see messages for yourself in the newspaper or on TV?**
- Do you occasionally feel that some events or incidents have a special meaning particularly for you?

Delusional misinterpretation

- **Do you occasionally see a secret message in the way objects are arranged or in their labelling or colour or in the way things happen?**

Quotation of ideas

- **Do you find that something you have previously thought or discussed is quoted on TV or in the newspapers, or used in some other way to indicate a reference to you?**

Familiar people impersonated

- **Do you feel that the appearance of any people you know well has changed in ways that suggest that someone might be impersonating them?**

Delusions of persecution

- **Does anyone seem to be trying to harm you?**
  If YES are they particularly singling you out?
  - How do you experience this?
  - Does there seem to be a plot or a conspiracy behind it?
    - How do you recognise it?

1	The definition doesn't apply
2	Questionable – patient may be upper extreme of normal limits
3	1 or 2 delusions that are vague, uncrystallised and not tenaciously held. Delusions do not interfere with thinking, social relations or behaviour
4	Presence of either a kaleidoscopic array of poorly formed, unstable delusions **or** a few well formed delusions that occasionally interfere with patients thinking, social relations or behaviour.
5	Numerous well formed delusions that are tenaciously held and occasionally interfere with patients thinking, social relations or behaviour
6	Stable set of delusions that clearly interfere with patients thinking, social relations and behaviour
7	Highly systemised or very numerous stable delusions, that dominate major facets of patients life. Often results in inappropriate/irresponsible action that may jeopardise safety of patient or others.

P5 **Grandiosity** (exaggerated self-opinion and unrealistic convictions of superiority, including delusions of extraordinary abilities, wealth, knowledge, fame, power and moral righteousness)

- **How do you feel you compare to the average person? Better or worse?**
- **Do you have talents/abilities/special or unusual powers that most people don't have?**
  - For example, do you ever feel you read another person's mind?
- Do you consider yourself wealthy? Famous? Have you ever appeared on television, radio, movies or stage?
- Do you rate higher in terms of your moral standards?
  - Does this make you special in some respect?
- Do you have a special mission in life?
  - How did this come about?
- Are you a religious person?
  - What is your relationship with god?
  - Are you closer to god than others are?

1	The definition doesn't apply
2	Questionable – patient may be upper extreme of normal limits
3	Some expansiveness or boastfulness is evident, but without clear-cut grandiose delusions.
4	Feels Distinctly and unrealistically superior to others. Some poorly formed delusions about special status/abilities may be present but not acted upon.
5	Clear-cut delusions concerning remarkable abilities/status /power that influence patients attitude but not behaviour
6	Clear cut delusions of remarkable superiority involving more than 1 parameter (wealth, fame, knowledge) are expressed, notably influence interactions, and may be acted upon
7	Thinking, interactions and behaviour are dominated by multiple delusions of amazing ability/wealth/knowledge/fame/power/moral stature which may take on a bizarre quality.

P6 **Suspiciousness/Persecution** (unrealistic/exaggerated ideas of persecution are shown, as reflected in guardedness, a distrustful attitude, suspicious hypervigilance, or delusions that others mean one harm

- **How do you feel you get along with other people?**
- **Do you like other people? Dislike people?**
  - If patient dislikes people :
    - Do you get particularly annoyed with people?
    - Afraid of people? Why?
- **Do you feel most people like you? Dislike you? Why?**
- **Do you trust most people you know?**
  - Are there some whom you distrust? Who? Why?
- **Do you ever feel some people talk about you behind your back?**
  - What do you think they say? Why?
- **Do you ever feel some people spy on you/plot against you/attempt to harm you/attempt to kill you?**
  - What is the evidence for this?
  - Who is behind all this?

- Why does it happen?

1	The definition doesn't apply
2	Questionable – patient may be upper extreme of normal limits
3	Presents a guarded or openly distrustful attitude, but thoughts/interactions/behaviour are minimally affected.
4	Distrustfulness is clearly evident, intrudes on interview and his/her behaviour, but there is no evidence of persecutory delusions. **Or** loosely formed persecutory delusions which do not seem to affect patients' attitude/interpersonal relations.
5	Patient shows marked distrustfulness, leading to major disruptions in interpersonal relations. **Or** clear cut delusions that have limited impact on his/her interpersonal relations and behaviour.
6	Clear cut pervasive delusions of persecution which may be systematised and that significantly interfere in patients interpersonal relations
7	A network of systemised persecutory delusions dominates the patients thinking, social relations and behaviour

☐ **P7** **Hostility** (verbal & non-verbal expressions of anger and resentment, including sarcasm, passive-aggressive behaviour, verbal abuse and assaultiveness

- **How have you been getting along with people lately? (family, co-workers etc)**
  If patient hasn't been getting on well with people – why?
- **Have you been irritable or grumpy lately?**
  If YES, does this lead to arguments with others even about minor issues, which normally wouldn't bother you?
    - Were you ever so irritable that you would shout out at people or start arguments or fights?

1	The definition doesn't apply
2	Questionable – patient may be upper extreme of normal limits
3	Indirect or restrained communication of anger (e.g. sarcasm, disrespect, hostile expressions or occasional irritability)
4	Patient presents an overtly hostile attitude showing frequent irritability and direct expression of anger or resentment
5	Highly irritable and occasionally verbally abusive or threatening
6	Uncooperativeness and verbal abuse or threats notably influence the interview and seriously impact upon patients social relations. Patient may be violent and destructive but not physically assaultive towards others
7	Marked anger results in extreme uncooperativeness precluding other interactions, or in episodes of physical assault towards others.

P3 **Hallucinatory behaviour** (verbal report or behaviour indicate perceptions that are not generated by external stimuli. May be auditory, visual, olfactory or somatic)

- **Do you ever have strange experiences/hear strange noises or sometimes hear things that others don't hear?**
- **Do you sometimes receive personal communications from the radio or television?**
- **Can you sometimes hear your thoughts aloud in your head? Do they sound like voices?**
  If patient hears voices:
  - How many are there?
  - Do they speak to you, comment about you, or speak to each other?
  - What do the voices say?
  - Are they good or bad voices?
  - Are you afraid of them?
  - Do the voices tell you what to do? Give you direct orders?
    - Do you obey the voices' commands? Must you?
- **Do ordinary things ever appear strange or distorted or do you ever have visions or see things others don't?**
  If YES,
  - How often?
  - How clear are these visions?
  - Do the visions occur together with the voices or separately?
- **Do you ever smell things that others don't?**
- **Do you ever get strange sensations from within your body or feel something strange inside you?**

If patient reports voices or visions, explore further with:

- What do you make of these voices / visions etc…?
- How did they come about?
- Are they a problem?

1	The definition doesn't apply
2	Questionable pathology; may be at the upper extreme of normal limits
3	1 or 2 clearly formed but infrequent hallucinations **or** a number of vague abnormal perceptions which do not result in distortions of thinking or behaviour.
4	Hallucinations occur frequently but not continuously, and the patients thinking and behaviour are affected only to a minor extent.
5	Hallucinations are frequent, may involve more than one sensory modality, and tend to distort thinking and/or disrupt behaviour. Patient may have a delusional interpretation of these experiences and respond to them emotionally and, on occasion, verbally as well.
6	Hallucinations are present almost continuously, causing major disruption of thinking and behaviour. Patient treats these as real perceptions, and functioning is impeded by frequent emotional and verbal responses to them.
7	Patients is almost totally preoccupied with hallucinations, which virtually dominate thinking and behaviour. Hallucinations are provided a rigid delusional interpretation and provoke verbal and behavioural responses, including obedience to command hallucinations.

G13 **Disturbance of volition** (disturbance in wilful initiation, sustenance, and control of one's thoughts, behaviour, movements and speech.

- **Do you find it difficult to make decisions in your day to day life?**
  - If YES, has this occurred in the last week?
  - Example?
- **Do you find your behaviour is sometimes aimless and disconnected, so that your daily routine is chaotic, because you are unable to plan your actions properly?**
  - If answer YES to any of these, explore further, ask for an example/why do you think this is etc.

1	The definition doesn't apply
2	Questionable pathology – patient may be upper extreme of normal limits
3	Some evidence of indecisiveness in conversation and thinking that may impede verbal and cognitive processes to a minor extent
4	The patient is often ambivalent and shows clear difficulty reaching decisions. Conversation may be marred by thinking alteration, and consequently, his or her verbal and cognitive functioning are clearly impaired.
5	Disturbance of volition interferes in behaviour and thinking. Pronounced indecision that impedes the initiation and continuation of social and motor activities, and which may be evidenced in halting speech
6	Execution of simple automatic motor functions (e.g. dressing/grooming) is interfered with, and speech is markedly affected.
7	Almost complete failure of volition is manifested by severe inhibition of movement and speech.

G10 **Disorientation** (lack of awareness of one's relationship to one's surroundings, including persons, places, and time that may be due to confusion or withdrawal)

- Do you know what day it is today?
- Month?
- Year?
- Season?
- Date?
- Where we are?

1	The definition doesn't apply
2	Questionable pathology – patient may be upper extreme of normal limits
3	General orientation is adequate but patient may have difficult with specifics, for example knows their location but not street address, knows hospital staff names but not their function, knows month but confuses day of the week. There may be narrowing of interest evidenced by familiarity with immediate but not extended milieu (ie identifies the staff but not Prime Minister etc).

4	Only partial success in recognising persons, places and time. For example, patient knows they are in a hospital but it's name, knows name of primary therapist but not many other direct care worker, knows year but not sure of month.
5	Considerable failure in recognising persons, places and time, for example has only vague notion of their whereabouts, and unfamiliar with most people in their milieu. May know year but not month, day or season.
6	Marked failure in recognising persons, places and time. (no knowledge of whereabouts, confuses date, can only name 1 or 2 individuals in current life.
7	Complete disorientation with regard to persons, places and time. Gross confusion or total ignorance about location, the current year, and even the most familiar people, such as parents, spouse, therapist etc.

☐ **N5** **Difficulty in abstract thinking** (impairment in abstract-symbolic thinking, as demonstrated by difficulty in classification, forming generalisations, and moving beyond concrete or egocentric thinking in problem solving tasks)

(See appendix I for list)

1	The definition doesn't apply
2	Questionable – patient may be upper extreme of normal limits
3	Tends to give literal or personalised interpretations to the more difficult proverbs, and some problems with concepts that are fairly abstract or remotely related
4	Often utilises concrete mode. Difficulty with most proverbs and some categories. Tends to be distracted by functional aspects and salient features.
5	Patient deals primarily in concrete mode, exhibiting difficulty with most proverbs and many categories.
6	Unable to grasp abstract meaning of proverbs or figurative expressions and can formulate classifications for only the most simple of similarities. Thinking is either vacuous or locked into functional aspects, salient features, and idiosyncratic interpretations.
7	Only uses concrete thinking modes. No comprehension of proverbs, common metaphors or similes and simple categories. Event salient and functional attributes do not serve as a basis for classification. This rating may apply to those who cannot interact even minimally with the interviewer due to marked cognitive impairment.

G9 **Unusual thought content** (thinking is characterised by strange or bizarre ideas, ranging from those that are remote/atypical to those that are distorted and absurd)

Basis for rating: Thought content expressed during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Thought content is somewhat peculiar or idiosyncratic, or familiar ideas are framed in an odd context.
4	Ideas are frequently distorted and occasionally seem quite bizarre.
5	Patient expresses many strange and fantastic thoughts (eg. Being adopted son of a king, being an escapee from death row) or some which are patently absurd (eg. Having hundreds of children, receiving radio messages from space via a tooth filling).
6	Patient expresses many illogical or absurd ideas or some which have a distinctly bizarre quality (eg having 3 heads, being a visitor from another planet).
7	Thinking is replete with absurd, bizarre and grotesque ideas.

N3 **Poor rapport** (lack of interpersonal empathy, openness in conversation, and a sense of closeness, interest, or involvement with the interviewer. This is evidenced by interpersonal distancing and reduced verbal and nonverbal communication)

Interpersonal behaviour during the course of interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Conversation is characterised by a stilted, strained, or artificial tone. It may lack emotional depth or tend to remain on an impersonal, intellectual plane.
4	Patient typically is aloof, with interpersonal distance quite evident. Patient may answer questions mechanically, act bored, or express disinterest.
5	Disinvolvement is obvious and clearly impedes the productivity of the interview. Patient may tend to avoid eye or face contact.
6	Patient is highly indifferent, with marked interpersonal distance. Answers are perfunctory, and there is little nonverbal evidence of involvement. Eye and face contact are frequently avoided.
7	Patient is totally uninvolved with the interviewer. Patient appears to be completely indifferent and consistently avoids verbal and nonverbal interactions during the interview.

N2 **Emotional withdrawal** (lack of interest in, involvement with and affective commitment to life events)

Observation of interpersonal behaviour during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Usually lacks initiative and occasionally may show deficient interest in surrounding events.
4	Patient is generally distanced emotionally from the milieu and its challenges but, with encouragement, can be engaged.
5	Patient is clearly deattached emotionally from persons and events in the milieu, resisting all efforts at engagement. Patient appears distant, docile, and purposeless but can be involved in communication at least briefly and tends to personal needs, sometimes with assistance.
6	Marked deficiency of interest and emotional commitment results in limited conversation with others and frequent neglect of personal functions, for which the patient requires supervision.
7	Patient is almost totally withdrawn, uncommunicative, and neglectful of personal needs as a result of profound lack of interest and emotional commitment.

N4 **Passive/apathetic social withdrawal** (diminished interest and initiative in social interactions due to passivity, apathy, anergy or avolition leading to reduced interpersonal involvements and neglect of daily living activities). Reports from others only.

How do you spend your time these days? Do you prefer to be alone?

Do you join in on activities with others?

(if not) Why not?

Do you have many friends?

(If no) do you have any friends?

Do you have any close friends?

How often do you see them?

(if not) Why not?

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Shows occasional interest in social activities but poor initiative. Usually engages with others only when approached first by them.
4	Passively goes along with most social activities but in a disinterested or mechanical way. Tends to recede into the background.
5	Passively participates in only a minority of activities and shows virtually no interest or initiative. Generally spends little time with others.
6	Tends to be apathetic and isolated, participating very rarely in social activities and occasionally neglecting personal needs. Has very few spontaneous social contacts.
7	Profoundly apathetic, socially isolated, and personally neglectful.

☐ **G16** **Active social avoidance** (diminished social involvement associated with unwarranted fear, hostility or distrust).Reports from others only.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Patient seems ill at ease in the presence of others and prefers to spend time alone, although she/he participates in social functions when required.
4	The patient begrudgingly attends all or most social activities but may need to be persuaded or may terminate prematurely on account of anxiety, suspiciousness, or hostility.
5	Patient fearfully and angrily keeps away from many social interactions despite others' efforts to engage them. Tends to spend unstructured time alone.
6	Patient participates in very few social activities because of fear, hostility or distrust. When approached, the patient shows a strong tendency to break off interactions, and generally tends to isolate themselves.
7	Patient cannot be engaged in social activites because of pronounced fears, hostility, or persecutory delusions. Avoids all interactions and remains isolated from others.

P2 **Conceptual disorganisation** (Disorganised process of thinking characterised by disruption of goal-directed sequencing, eg., circumstantiality, tangentiality, loose associations, non-sequiturs, thought block or gross illogicality.

Basis for rating: Cognitive verbal processes observed during the course of interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Thinking is circumstantial, tangential, or paralogical. There is some difficulty in directing thoughts toward a goal, and some loosening of associations may be evidenced under pressure.
4	Able to focus thoughts when communications are brief and structured, but becomes loose or irrelevant when dealing with more complex communications or when under minimal pressure.
5	Generally has difficulty in organising thoughts, as evidenced by frequent irrelevancies, disconnectedness, or loosening of associations, even when not under pressure.
6	Thinking is seriously derailed and internally inconsistent, resulting in gross irrelevancies and disruption of thought processes, which can occur almost constantly.
7	Thoughts are disrupted to the point where the patient is incoherent. There is marked loosening of associations, which results in total failure of communication, eg., 'word salad', or mutism.

G7 **Motor retardation** (Reduction in motor activity reflected by the slowing or lessening of movements and speech, diminished responsiveness to stimuli, and reduced body tone).

Basis for rating: manifestations during the course of the interview

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Slight but noticeable diminution in rate of movements and speech; patient may be somewhat unproductive in conversation and gestures.
4	Patient is clearly slow in movements, and speech may be characterised by poor productivity, including long response latency, extended pauses, or slow pace.
5	A marked reduction in motor activity renders communication highly unproductive or delimits functioning in social and occupational situations. Patient can usually be found sitting or lying down.
6	Movements are extremely slow, resulting in a minimum of activity and speech. Essentially the day is spent idly or lying down.
7	Patient is almost completely immobile and virtually unresponsive to external stimuli.

N6 **Lack of spontaneity and flow of conversation** (reduction in the normal flow of communication associated with apathy, avolition, defensiveness, or cognitive deficit. This is manifested by diminished fluidity and productivity of the verbal-interactional process.

Rating based on cognitive-verbal processes observed during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Conversation shows little initiative. Patients answers tend to be brief and unembellished, requiring direct and leading questions by the interviewer.
4	Conversation lacks free flow and appears uneven or halting. Leading questions are frequently needed to elicit adequate responses and proceed with conversation.
5	Patient shows a marked lack of spontaneity and openness, replying to the interviewers questions with only one or two brief sentences.
6	Patient's responses are limited mainly to a few words or short phrases intended to avoid or curtail communication (eg 'I don't know', 'I'm not at liberty to say'). Conversation is seriously impaired as a result, and the interview is highly unproductive.
7	Verbal output is restricted to, at most, an occasional utterance, making conversation not possible.

N7 **Stereotyped thinking** (decreased fluidity, spontaneity, and flexibility of thinking, as evidenced in rigid, repetitious, or barren thought content)

Rated on cognitive verbal processes observed during the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Some rigidity shown in attitudes or beliefs. Patient may refuse to consider alternative positions or have difficulty in shifting from one idea to another.
4	Conversation revolves around a recurrent theme, resulting in difficulty in shifting to a new topic.
5	Thinking is rigid and repetitious to the point that, despite the interviewers efforts, conversation is limited to only two or three dominating topics.
6	Uncontrolled repetition of demands, statements, ideas, or questions which severely impairs conversation.
7	Thinking, behaviour, and conversation are dominated by constant repetition of fixed ideas or limited phrases, leading to gross rigidity, inappropriateness and restrictiveness of patients communication.

N1 **Blunted affect** (diminished emotional responsiveness characterised by a reduction in facial expression, modulation of feelings, and communicative gestures).

Observed manifestations of affective tone and emotional responsiveness during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Changes in facial expression and communicative gestures seem to be stilted, forced, artificial, or lacking in modulation.
4	Reduced range of facial expression and few expressive gestures result in a dull appearance.
5	Affect is generally 'flat', with only occasional changes in facial expression and paucity of communicative gestures.
6	Marked flatness and deficiency of emotions exhibited most of the time. There may be unmodulated extreme affective discharges, such as excitement, rage, or inappropriate uncontrolled laughter.
7	Changes in facial expression and evidence of communicative gestures are virtually absent. Patient seems constantly to show a barren or 'wooden' expression.

P4 **Excitement** (hyperactivity is reflected in accelerated motor behaviour, heightened responsivity to stimuli, hypervigilance, or excessive mood lability.)

Rating based upon behavioural manifestations during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Tends to be slightly agitated, hypervigilant or mildly overaroused throughout the interview, but without distinct episodes of excitement or marked mood liability. Speech may be slightly pressured.
4	Agitation or overarousal is clearly evident throughout the interview, affecting speech and general mobility or episodic outbursts occur sporadically.
5	Significant hyperactivity or frequent outbursts of motor activity are observed, making it difficult for the patient to sit longer than several minutes at any given time.
6	Marked excitement dominates the interview, delimits attention and to some extent affects personal functions such as eating or sleeping.
7	Marked excitement seriously interferes in eating and sleeping and makes interpersonal interactions virtually impossible. Acceleration of speech and motor activity may result in incoherence and exhaustion.

G5 **Mannerisms and posturing** (unnatural movements or posture are shown as characterised by an awkward, stilted, disorganised, or bizarre appearance).

Ratings based on the observation of physical manifestations during the course of interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Slight awkwardness in movements or minor rigidity of posture.
4	Movements are notably awkward or disjointed, or an unnatural posture is maintained for brief periods.
5	Occasional bizarre rituals or contorted posture are observed, or an abnormal position is sustained for extended periods.
6	Frequent repetition of bizarre rituals, mannerisms, or stereotyped movements, or a contorted posture is sustained for extended periods.
7	Functioning is seriously impaired by virtually constant involvement in ritualistic, manneristic, or stereotyped movements or by an unnatural fixed posture which is maintained most of the time.

G14 **Poor impulse control** (there is disordered regulation and control when acting on inner urges, resulting in sudden, unmodulated, arbitrary, or misdirected discharge of tension and emotions without concern about the consequences.

Basis for rating: Behaviour during the course of the interview or else otherwise reported.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Patient tends to be easily angered and frustrated when facing stress or denied gratification but rarely acts on impulse.
4	Patient get angered and verbally aggressive with minimal provocation. May be occasionally threatening, destructive, or have one or two episodes involving physical confrontation or a minor brawl.
5	Patient exhibits repeated impulsive episodes involving verbal abuse, destruction of property, or physical threats. There may be one or two episodes involving serious assault, for which the patient requires isolation, physical restraint, or sedation.
6	Patient frequently is impulsively aggressive, threatening, demanding, and destructive, without any apparent consideration of consequences. Shows assaultive behaviour and may also be sexually offensive and possibly respond behaviourally to hallucinatory commands.
7	Patient exhibits homicidal attacks, sexual assaults, repeated brutality, or self-destructive behaviour. Requires constant direct supervision or external constraints because of inability to control dangerous impulses.

G4 Tension (There are overt physical manifestations of fear, anxiety, and agitation, such as stiffness, tremors, profuse sweating, and restlessness).

Based upon verbal report attesting to anxiety, and thereupon the severity of physical manifestations of tension observed during the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Posture and movements indicate slight apprehensiveness, such as minor rigidity, occasional restlessness, shifting of position, or rapid hand tremor.
4	A clearly nervous appearance emerges from various manifestations, such as fidgety behaviour, obvious hand tremor, excessive perspiration, or nervous mannerisms.
5	Pronounced tension is evidenced by numerous manifestations, such as nervous shaking, profuse sweating, and restlessness, but conduct in the interview is not significantly affected.
6	Pronounced tension to the point that interpersonal interactions are disrupted. The patient, for example, may be constantly fidgeting, unable to sit still for long, or show hyperventilation.
7	Marked tension is manifested by signs of panic or gross motor acceleration, such as rapid restless pacing an inability to remain seated for longer than a minute, which makes sustained conversation not possible.

G8 **Uncooperativeness** (active refusal to comply with the will of significant others, including the interviewer, hospital staff, or family, perhaps associated with distrust, defensiveness, stubbornness, negativism, rejection of authority, hostility, or belligerence.

Basis for rating: Interpersonal behaviour observed during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Complies with an attitude of resentment, impatience, or sarcasm. May inoffensively object to sensitive probing during the interview.
4	Occasional outright refusal to comply with normal social demands, such as making own bed, scheduled appointments etc. The patient may project a hostile, defensive, or negative attitude but usually can be worked with.
5	Patient is frequently noncompliant with the demands of his/her milieu and may be characterised by others as an 'outcast' or having a serious 'attitude problem'. Uncooperativeness is reflected in obvious defensiveness or irritability with the interviewer and may be unwilling to address many questions.
6	Patient is highly uncooperative, negativistic, and possibly also belligerent. Refuses to comply with most social demands and may be unwilling to initiate or conclude the full interview.
7	Active resistance seriously impact on virtually all major areas of functioning. Patient may refuse to join in any social activities, tend to personal hygiene, converse with family or staff, and participate even briefly in an interview.

G11 **Poor attention** (poor focussed alertness is manifested by poor concentration, distractibility from internal and external stimuli, and difficulty in harnessing, sustaining, or shifting focus to new stimuli.)

Basis for rating: Manifestations during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Limited concentration evidenced by occasional vulnerability to distraction or faltering attention toward the end of the interview.
4	Conversation is affected by the tendency to be easily distracted, difficulty in long sustaining concentration on a given topic, or problem shifting attention on to new topics.
5	Conversation is seriously hampered by poor concentration, distractibility, and difficulty in shifting focus appropriately.
6	Patients attention can be harnessed for only brief moments or with graet effort, due to marked distraction by internal or external stimuli.
7	Attention is so disrupted that even brief conversation is not possible.

G15 **Preoccupation** (there is an absorption with internally generated thoughts and feelings or with autistic experiences to the detriment of reality orientation and adaptive behaviour.

Interpersonal behaviour reported during the course of the interview.

1	The definition doesn't apply
2	Questionable pathology; patient may be upper extreme of normal limits
3	Excessive involvement with personal needs or problems, such as that conversation veers back to ego-centric themes and there is diminished concern exhibited toward others.
4	Patients occasionally appears self-absorbed, as if daydreaming or involved with internal experiences, which interferes with communication to a minor extent.
5	Patient often appears to be engaged in autistic experiences, as evidenced by behaviours that significantly intrude on social and communicational functions, such as the presence of a vacant stare, muttering or talking to oneself, or involvement with stereotyped motor patterns.
6	Marked preoccupation with autistic experiences, which seriously delimits concentration, ability to converse, and orientation to the milieu. The patients frequently may be observed smiling, laughing, muttering, talking or shouting to oneself.
7	Gross absorption with autistic experiences, which profoundly affects all major realms of behaviour. The patient constantly may be responding verbally and behaviourally to hallucinations and show little awareness of other people or the external milieu.

Questions for assessing Abstract thinking:

Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	1. How are a ball and orange alike? 2. Apple and banana? 3. Pencil and pen? 4. Nickel and dime?
Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	5. Table and chair? 6. Tiger and elephant? 7. Hat and shirt? 8. Bus and train?
Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	9. Arm and leg? 10. Rose and tulip? 11. Uncle and cousin? 12. The sun and the moon?
Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	13. Painting and poem? 14. Hilltop and valley? 15. Air and water? 16. Peace and prosperity?

-What does the saying mean?

Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	1. “Plain as the nose on you face”? 2. “Carrying a chip on your shoulder”? 3. “Two heads are better than one”? 4. “Two many cooks spoil the broth”?
Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	5. “Don’t judge a book by its cover”? 6. “One man’s food is another man’s poison”? 7. “All that glitters is not gold”? 8. “Don’t cross the bridge until you come to it”?
Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	9. “What’s good for the goose is good for the gander”? 10. “The grass always looks greener on the other side”? 11. “Don’t keep all your eggs in one basket”? 12. “One swallow does not make a Summer”?
Eligibility assessment **Baseline assessment** **EoT assessment** **6mnth FU assessment**	13. “A stitch in time saves nine”? 14. “A rolling stone gathers no moss”? 15. “The acorn never falls far from the tree”? 16. “People who live in glass houses should not throw stones at others”?

CAINS (v1.0)

ID: _____ DATE: _____ RATER: _____

Overall Introduction: ***In this interview, I'll be asking you some questions about things you have been doing over the past week. In the first section, I'm going to ask you some questions about your family, romantic partners, and friends, including how motivated you have been to spend time with them and how you felt when you were around them.***

I. SOCIAL (MOTIVATION & PLEASURE)

ITEM 1: MOTIVATION FOR CLOSE FAMILY/SPOUSE/PARTNER RELATIONSHIPS

[Note: Romantic relationships can be rated in either Item 1 or Item 2 but NOT both. A spouse/ partner relationship in which the couple is living together should be assessed in Item 1. A dating/romantic relationship in which the couple is not living together should be assessed in Item 2.]

The following questions are about your family. This can include relatives like parents, brothers or sisters and other relatives, as well as your spouse [if married] or live-in partner. Have you been in contact with or visited with any family members in the past week (in person, phone, email)? Any contact with a spouse or partner?

IF CONTACT:

- *Who have you been in contact with? Anybody else?*
- *What things have you done with your family?*
- *IF RELEVANT: What things have you done with your spouse/partner?*
- *How much time did you spend together?*

Behavior

- *What have you done to see or contact your [family/spouse/partner] in the past week?*
- *When you were with your [family/spouse/partner] who decided what you would do?*
- *Who started the conversation? Did you start it? Did your [family/spouse/partner]? Were you involved in the conversation?*
- *Did you ever find that you quickly wanted to end your interactions with your [family/spouse/partner]? Did you want them to last longer?*

Motivation & Interest in Closeness

- *Have you been motivated to be around or in touch with your [family/spouse/partner] in the past week? (Why is that?)*
- *What did you talk about? Can you talk about good and bad times with your [family/spouse/partner]?*
- *How close do you feel to your [family/spouse/partner]? What does being close mean for you?*
- *Were there times in the past week when you just didn't want to be around or in touch with your [family/spouse/partner]?*
- *How important is being part of a family to you?*
- *What about that is important to you? Have you felt this way throughout the past week?*

IF NO FAMILY CONTACT:

[NOTE: This section applies when not part of a close family or if available relatives could be contacted but person has chosen not to interact. If the person is not currently in a relationship with a live-in spouse/partner, interest in romantic relationships is assessed in Item 2.]

- *Has your family tried to contact you or visit you in the last week?*
- *Has anything kept you or held you back from being in contact with your family?*
- *Do you wish you were closer to your family? OR Do you wish you were part of a close family?*
- *Did you miss interacting with your family in the past week?*
- *Is having a relationship with your family important to you? What about having a relationship is important to you?*
- *Have you preferred to spend your time alone rather than with your family?*

Item 1 – Motivation for Close Family/Spouse/Partner Relationships

0 = No impairment: VERY INTERESTED in and highly values close family bonds as one of the most important parts of life. Strongly desires and is highly motivated to be in contact with family. Regularly initiates and persists in interactions with family and actively engages in these interactions; good and bad times are openly discussed. Well within normal limits.

1 = Mild deficit: GENERALLY INTERESTED in and values close family bonds though response suggests some minor or questionable reduction. Generally desires and is motivated to maintain contact with family. Has a close relationship with family member(s) in which good and bad times can be discussed. Mild deficit in initiating and persisting in regular interactions with family – generally actively engaged when interactions occur.

2 = Moderate deficit: SOMEWHAT INTERESTED in family relationships and considers them somewhat important. May occasionally miss close connections with family but is only somewhat motivated to seek out interaction with family. Notable deficit in initiating and persistently engaging in interactions; discussion of good and bad times is limited. Interactions with family members may occur but are largely superficial and participation is best characterized as "going through the motions"; interactions are more likely initiated by family with mostly passive involvement of the person.

3 = Moderately severe deficit: LITTLE INTEREST in family relationships (could "take it or leave it") and does not describe family bonds as important. Describes hardly any motivation and minimal effort to have close family relationships. Rarely has discussion of good and bad times with family members. Contact and engagement with family is superficial and passive with almost all initiation and efforts to engage coming from others.

4 = Severe deficit: NO INTEREST in family relationships and does not consider them at all important. Prefers to be alone and is not at all motivated to be with family. If person does see family, it is done so grudgingly, passively and with no interest.

ITEM 2: MOTIVATION FOR CLOSE FRIENDSHIPS & ROMANTIC RELATIONSHIPS

Let's talk about friends (and dating or romantic relationships) now. By friends, I mean people who you know and spend time with, anyone you consider a friend, or people you can rely on and count on. Have you had any contact with friends in the last week (in person, phone, email)? IF RELEVANT: have you been in contact with a romantic partner or dating in the last week?

IF CONTACT:

- *In the past week, what have you done with your [friends/partner/dates]?*
- *Tell me about what you did [or what you talked about] during that [visit, activity, conversation]?*
- *How much time did you spend together with [friends/partners/dates]?*

Behavior

- What steps did you take to see or contact your [friends/partner/dates] in the past week?
- When you were with your [friends/partner/dates], who decided what you would do?
- When you spoke with your [friends/partner/dates], who started the conversation? Did you?
- Did you ever find that you quickly wanted to end your interaction with your [friends/partner/dates]? Did you want them to last longer?

Motivation & Interest in Closeness

- *Have you been motivated to be around your friends* (partner/dates) *in the past week? Why is that?*
- *Can you talk about both good times and bad times?*
- *Were there times in the past week when you just didn't feel like being around your friends* (partner/dates)*?*
- *How important is having friendships* (partner/dates) *to you? What about that is important to you?*
- *How close do you feel to your friends* (partner/dates)*? What does being close mean for you?*

IF NO FRIENDS/ROMANTIC CONTACT:

• *Are you interested in having friends or dating?*
• *Is having friendships [or being in a romantic relationship] important to you? If Yes, what about [specify friendships/romantic partner] is important?*
• *Did you miss these types of relationships in the past week?*
• *Would you like to have friends [or a romantic partner] with whom you could talk about good and bad times?*
• *(If any indication of interest) Have you taken any steps to meet someone who might be a friend (or romantic partner)?*
• *Has anything kept you or held you back from being in contact with your friends?*
• *Would you prefer to have friendships [or a romantic relationship] or would you prefer to be alone?*

Item 2 – Motivation for Close Friendships & Romantic Relationships

0 = No impairment: VERY INTERESTED in and highly values friend/romantic relationships as one of the most important parts of life. Strongly desires and is very motivated to engage in friendships. Regularly initiates and persists in interactions with friends/partner and actively engages in these interactions; good and bad times are openly discussed. Well within normal limits.

1 = Mild deficit: GENERALLY INTERESTED in and values friend/romantic relationships though response suggests some minor or questionable reduction. Generally desires and is motivated to engage in friendships. Has friendships/relationship in which good and bad times can be discussed though this may be less consistent. Mild deficit in initiating or persistently engaging during interactions with friends/partner. If no friends/relationship, misses friend/romantic relationships, is motivated to have friends/relationship, and makes efforts to seek out friends/relationship.

2 = Moderate deficit: SOMEWHAT INTERESTED in friend/romantic relationships and considers them somewhat important. May occasionally miss close connections with friends/partner and is somewhat motivated to have friends/partner. Notable deficit in initiating and persistently engaging in interactions; discussion of good and bad times is limited. Interactions with friends/romantic partner may occur but are largely superficial and participation is best characterized as "going through the motions"; interactions are initiated by others with mostly passive involvement of the person. If no friend/romantic relationships, is only somewhat motivated to have friends/partner and rarely if ever seeks out friends/partner.

3 = Moderately severe deficit: LITTLE INTEREST in friend/romantic relationships (could "take it or leave it") and does not describe friends/partner as important. Describes hardly any motivation to have friendships, and would just as soon be alone. Contact and engagement with others is superficial and passive with almost all initiation and efforts to engage coming from others.

4 = Severe deficit: NO INTEREST in friend/romantic relationships and does not consider them at all important. Prefers to be alone and is not at all motivated to have friends/partner.

ITEM 3: FREQUENCY OF PLEASURABLE SOCIAL ACTIVITIES – *PAST* WEEK

[NOTE: Ratings are based on **NUMBER OF DAYS IN THE WEEK** that pleasurable activity with other people is experienced. When there are reports of several different activities occurring, clarify if these happened on same or different days.]

Now, I want to talk to you about how you felt during the times you spent with or were in contact with others during the past week. You can include times with any of the people we have talked about so far or anyone else. Did you have any enjoyable interactions with other people, such as:

• *Family* (PAUSE)
• *Romantic or dating partners* (PAUSE)
• *Friends* (PAUSE)
• *Any other enjoyable social interactions or time spent with people*? (PAUSE)
• *IF NEEDED: Ask about people brought up in other sections* ***that were described as enjoyable interactions***

IF YES:

• *What about that was enjoyable?*
• *How many days did you enjoy/get pleasure from these interactions [time spent with xx person(s)] (for each)?*
• [If many (i.e., 5 or 6) days mentioned or if not clear which days of week interactions were enjoyed] *Were there any days that you did not have enjoyable interactions with other people?*

Item 3 – Frequency of Pleasurable Social Activities – Past Week

0 = No impairment: Pleasure experienced daily.
1 = Mild deficit: Pleasure experienced 5-6 days.
2 = Moderate deficit: Pleasure experienced 3-4 days.
3 = Moderately severe deficit: Pleasure experienced 1-2 days.
4 = Severe deficit: No pleasure reported

ITEM 4: FREQUENCY OF EXPECTED PLEASURABLE SOCIAL ACTIVITIES – *NEXT* WEEK
[NOTE: Ratings are based on total **NUMBER OF EXPECTED PLEASURABLE ACTIVITIES**, regardless of days on which they are expected to occur].

Now I would like you to think ahead to NEXT week (next 7 days), thinking about whom you will spend time with. You can include people you have already talked about or anyone else. What do you think you will enjoy doing in the NEXT week with other people?

FOR EACH ANSWER PROVIDED:

• *What about it do you expect to enjoy?*
• *How often do you think you will enjoy this in the next week?*

FOLLOW UP
• *Are there other experiences with people you think you will enjoy in the next week?*

ITEM 4 – Frequency of Expected Pleasurable Social Activities – Next week

0 = No impairment: Expecting MANY (7 or more) pleasurable experiences.
1 = Mild deficit: Expecting enjoyment from SEVERAL (5-6) pleasurable experiences.
2 = Moderate deficit: Expecting enjoyment from a FEW (3-4) pleasurable experiences.
3 = Moderately severe deficit: Expecting a COUPLE (1-2) pleasurable experiences.
4 = Severe deficit: Expecting NO pleasurable experiences.

II. WORK & SCHOOL (MOTIVATION & PLEASURE)

ITEM 5: MOTIVATION FOR WORK & SCHOOL ACTIVITIES
Now I am going to ask you some questions about work and school, including how motivated you have been for work or school activities and how you felt while doing these things over the past week. Have you been working or going to school over the past week? Any volunteer work? Are you in a work-related treatment program?

IF IN A RELEVANT ROLE:
• *Tell me about what you do in your [insert role here]*
• *How much time has this involved over the past week?*

Behavior
• *Have you been able to complete tasks at [insert role here]?*
• *In the past week has anyone raised any concerns with your [insert role here] performance?*
• *Have you missed any days in the past week? Why?*
• *Does someone need to remind you about [insert role here]? Why is that?*
• *Were there things you meant to do or were supposed to do but just never got around to doing them? Why?*

Motivation
- *How do you feel about [insert role here]?*
- *Have you been motivated to do your [insert role here]?*
- *What motivates you to do your [insert role here]?*
- *Were there times during the past week when you just didn't feel like [insert role here]?*
- *How important is your [insert role here] to you? What about it is important?*

IF NO CURRENT ROLE:
- *Is there a reason why you are not currently (work/school/volunteer)?*
- *Has anything held you back from looking for (work/school/volunteer)?*
- *How do you feel about working or going to school or volunteering?*
- *Have you felt much interest in work/school/volunteer? [Tell me more]*
- *Is working important to you? What about working/going to school/volunteering is important?*
- *Do you miss work/school/volunteer?*
- *Have you tried to take any steps to start working/going to school/volunteering? What steps have you taken? How often have you looked into work/school/volunteer?*

ITEM 5 – Motivation for Work & School Activities

0 = No impairment: Person is VERY MOTIVATED to seek out work or school, or new opportunities in work or school; initiates and persists in work, school, or job-seeking on a regular basis. Well within normal limits.
1 = Mild deficit: Person is GENERALLY MOTIVATED to seek out work or school or new opportunities in work or school; a mild deficit in initiating and persisting; may report instances of initiating, but with moderate persistence.
2= Moderate deficit: Person is SOMEWHAT MOTIVATED to seek out work or school or new opportunities in work or school; notable deficit in initiating; may have initiated activities, but needed reminders on multiple occasions, and/or not initiated any new activities, and/or not persisted for very long.
3 = Moderately severe deficit: Person is only SLIGHTLY MOTIVATED to seek out work or school or new opportunities in work or school; significant deficit in initiating; may have needed constant reminders, and/or initiated a few activities; did not persist for very long.
4 = Severe deficit: Person is NOT AT ALL MOTIVATED to seek out work / school; nearly total lack of initiation and persistence in work, school, or job seeking.

ITEM 6: FREQUENCY OF EXPECTED PLEASURABLE WORK & SCHOOL ACTIVITIES - *NEXT* WEEK
[NOTE: Ratings are based on total **NUMBER OF EXPECTED PLEASURABLE ACTIVITIES,** regardless of days on which they are expected to occur].
Now I would like you to think ahead to NEXT week (next 7 days); thinking about work/volunteer/school.

IF HAS A RELEVANT ROLE:
- *What do you think you will enjoy doing in the NEXT week at work/volunteer/school, etc.*

IF NO RELEVANT ROLE:
- *Do you think you will enjoy anything related to seeking paid or volunteer work, or school?*

FOR EACH ANSWER PROVIDED:
- *What about it do you expect to enjoy?*
- *How often do you think you will enjoy this in the next week?*

FOLLOW UP:
- *Are there other work/school experiences you think you will enjoy in the next week?*

ITEM 6 – Frequency of Expected Pleasurable Work & School Activities – *Next* Week

0 = No impairment: Expecting MANY (7 or more) pleasurable experiences.
1 = Mild deficit: Expecting enjoyment from SEVERAL (5-6) pleasurable experiences.
2 = Moderate deficit: Expecting enjoyment from a FEW (3-4) pleasurable experiences.
3 = Moderately severe deficit: Expecting a COUPLE (1-2) pleasurable experiences.
4 = Severe deficit: Expecting NO pleasurable experiences.

III. RECREATION (MOTIVATION & PLEASURE)

ITEM 7: MOTIVATION FOR RECREATIONAL ACTIVITIES

In the next section, I am going to ask you some questions about what you do in your free time – any hobbies or recreational activities. I will ask about your motivation and feelings about the things that you have done in your free time over the past week.

• *What have you done in your free time in the past week?*
• *Have you participated in any hobbies or leisure activities such as sports or games, going to church, TV, music, reading, internet, walking or other such activities during the past week?*

IF YES:

Behavior

• *Tell me about (activity). How much time has this involved over the past week? Did you want to do (activity) more than that? Did it last longer than you had hoped? Why did it only last for (xx)?*
• *Did anything get in the way of doing these activities over the past week? What was that?*
• *Who initiated these activities? Did someone need to remind you to participate in these activities?*

Motivation

• *How has your motivation or drive to get involved in these activities been over the past week?*
• *Did you ever feel like you just weren't very interested in these activities?*
• *Are these types of activities important to you? Why? Have you been interested in these activities?*
• *Did you ever feel that you would just as soon do nothing instead of getting involved in these types of activities?*

IF NO:

• *Is there a reason why you haven't gotten involved in any hobbies or recreational activities in the past week?*
• *Have you wanted to or were you motivated to do something with your free time in the past week?*
• *Did anything ever get in the way of doing these types of activities over the past week? What was that?*

ITEM 7 – Motivation for Recreational Activities

0 = No impairment: Person is VERY MOTIVATED to seek out hobbies and recreational activities; initiates and persists in hobbies and recreational activities on a regular basis, well within normal limits.
1 = Mild deficit: Person is GENERALLY MOTIVATED to seek out hobbies and recreational activities; a mild deficit in initiating and persisting; may report initiating hobbies, but with moderate persistence.
2 = Moderate deficit: Person is SOMEWHAT MOTIVATED to seek out hobbies and recreational activities; notable deficit in initiating; may have initiated some activities and/or not persisted for very long. Others were somewhat more likely to initiate hobbies or activities.
3 = Moderately severe deficit: Person is only SLIGHTLY MOTIVATED to seek out hobbies and recreational activities; significant deficit in initiating and persisting; may have initiated a few activities and not persisted for very long. Others were much more likely to initiate hobbies or prompt initiation.
4 = Severe deficit: Person is NOT AT ALL MOTIVATED to seek out hobbies and recreational activities; nearly total lack of initiation and persistence in hobbies or recreational activities.

ITEM 8: FREQUENCY OF PLEASURABLE RECREATIONAL ACTIVITIES – *PAST* WEEK

[NOTE: Rating is based on both **VARIETY** of pleasurable activities and **DAILY FREQUENCY** that these are experienced. When there are reports of several different activities occurring, need to clarify if these happened on same or different days.]

Did you have any enjoyable (pleasurable) experience from things you did in your free time last week? You can include any of the activities we've talked about so far or any other leisure activities in the past week, including TV, sports or games, going to church, music, reading, internet, walking or other such activities?

- *What about [insert activity here] was enjoyable?*
- *How many days did you enjoy/get pleasure from these experiences?*
- *IF NEEDED: Ask about activities brought up in other sections* ***that were described as enjoyable***

FOLLOW UP:
Any other enjoyable experiences from things you do in your free time or your hobbies?

ITEM 8 – Frequency of Pleasurable Recreational Activities - Past Week

0 = No impairment: At least A FEW (3) different types of pleasurable experiences, experienced daily.
1 = Mild deficit: At least A FEW (3) different types of pleasurable experiences, experienced more days than not.
2 = Moderate deficit: 1 or 2 different types of pleasurable experiences, experienced more days than not.
3 = Moderately severe deficit: 1 type of pleasurable experience, experienced on just a few days.
4 = Severe deficit: No pleasurable experiences.

ITEM 9: FREQUENCY OF EXPECTED PLEASURABLE RECREATIONAL ACTIVITIES – *NEXT* WEEK
[NOTE: Ratings are based on total **NUMBER OF EXPECTED PLEASURABLE ACTIVITIES,** regardless ofdays on which they are expected to occur]

Now I would like you to think ahead to NEXT week (next 7 days), thinking about your free time/hobbies/ recreation. You can include any of the activities you have already talked about or anything else. What do you think you will enjoy doing in the NEXT WEEK in your recreational/free time?

FOR EACH ANSWER PROVIDED:
- *What about it do you expect to enjoy?*
- *How often do you think you will enjoy [activity] in the next week?*

FOLLOW UP:
- *Are there other things you do in your free time like hobbies or recreational activities that you think you will enjoy in the next week?*

ITEM 9 – Frequency of Expected Pleasurable Recreational Activities – Next Week

0 = No impairment: Expecting MANY (7 or more) pleasurable experiences.
1 = Mild deficit: Expecting enjoyment from SEVERAL (5-6) pleasurable experiences.
2 = Moderate deficit: Expecting enjoyment from a FEW (3-4) pleasurable experiences.
3 = Moderately severe deficit: Expecting a COUPLE (1-2) pleasurable experiences.
4 = Severe deficit: Expecting NO pleasurable experiences.

IV. EXPRESSION

ITEM 10: FACIAL EXPRESSION

When making the facial expression rating, consider facial movements across all parts of the face, including in the eyes (e.g., raised brows when surprised), mouth (smiling or grimacing), and mid-face (e.g., wrinkled nose when disgusted).

ITEM 10 - Facial Expression

0 = No impairment: WITHIN NORMAL LIMITS; frequent expressions throughout the interview.
1 = Mild deficit: MILD DECREASE in the frequency of facial expressions, with limited facial expressions during a few parts of the interview.
2 = Moderate deficit: NOTABLE DECREASE in the frequency of facial expressions, with diminished facial expressions during several parts of the interview.
3 = Moderately severe deficit: SIGNIFICANT LACK of facial expressions, with only a few changes in facial expression throughout most of the interview.
4 = Severe deficit: NEARLY TOTAL LACK of facial expressions throughout the interview.

ITEM 11: VOCAL EXPRESSION

This item refers to prosodic features of the voice. This item reflects changes in tone during the course of speech. Speech rate, amount, or content of speech is not assessed.

Item 11 - Vocal Expression

0 = No impairment: WITHIN NORMAL LIMITS. Normal variation in vocal intonation across interview. Speech is expressive and animated.
1 = Mild deficit: MILD DECREASE in vocal intonation. Variation in intonation occurs with a limited intonation during a few parts of the interview.
2 = Moderate deficit: NOTABLE DECREASE in vocal intonation. Diminished intonation during several parts of the interview. Much of speech is lacking variability in intonation but prosodic changes occur in several parts of the interview.
3 = Moderately severe deficit: SIGNIFICANT LACK of vocal intonation with only a few changes in intonation throughout most of the interview. Most of speech is flat and lacking variability, only isolated instance of prosodic change.
4 = Severe deficit: NEARLY TOTAL LACK OF change in vocal intonation with characteristic flat or monotone speech throughout the interview.

ITEM 12: EXPRESSIVE GESTURES

Expressive gestures are used to emphasize what is communicated verbally through gestures made with the hands, head (nodding), shoulders (shrugging), and trunk (leaning forward, leaning back).

ITEM - 12 Expressive Gestures

0 = No impairment: WITHIN NORMAL LIMITS; uses frequent gestures throughout the interview.
1 = Mild deficit: MILD DECREASE in the frequency of expressive gestures, with limited gestures in a few parts of the interview.
2= Moderate deficit: NOTABLE DECREASE in the frequency of expressive gestures, with lack of gestures during several parts of the interview.
3 = Moderately severe deficit: SIGNIFICANT LACK of expressive gestures, with only a few gestures throughout most of the interview.
4 = Severe deficit: NEARLY TOTAL LACK of expressive gestures.

ITEM 13: QUANTITY OF SPEECH

This item refers to the quantity of words spoken. Other speech abnormalities, such as disorganization, neologisms, or psychotic content are not rated here. For instance, a disorganized person may produce a large quantity of speech and have a low (normal) score on this item.

ITEM - 13 Quantity of speech

0 = No impairment: NORMAL AMOUNT of speech throughout the interview. Replies provide sufficient information with frequent spontaneous elaboration.
1 = Mild deficit: MILD DECREASE in the quantity of speech, with brief responses during a few parts of the interview.
2= Moderate deficit: NOTABLE DECREASE in speech output, with brief responses during several parts of the interview.
3 = Moderately severe deficit: SIGNIFICANT LACK of speech, with very brief answers (only several words) in responses throughout most of the interview.
4 = Severe deficit: All or nearly all replies are one or two words throughout the entire interview.

The Manchester Short Assessment of Quality of Life (MANSA)

Date of birth ☐☐ ☐☐ ☐☐

Gender l=Male, 2=Female ☐

Ethnic origin ☐

l=White	5=Indian
2=Black Caribbean	6=Pakistani
3=Black African	7=Bangladeshi
4=Black other	8=Chinese
9=Other	

Diagnosis Use ICD 10 ☐☐☐☐

Section 2

In a first interview, ask all questions 1 to 9. In a repeat interview, ask first, whether there have been any changes in the respondent's circumstances as assessed in Section 2. If the answer is yes, complete questions 1 to 9. If the answer is no, go straight to Section 3.

1. Age at leaving full time education ☐☐

2. Employment status: ☐

l=In paid employment	4=Unemployed
2=In sheltered employment	5=Retired
3=Training/education is main occupation	6=Other

If employed, ask questions 3 and 4, otherwise go straight to question 5

3. What is your occupation? _____

4. How many hours a week do you work? ☐☐

5. What is your total monthly income after tax? ☐☐☐☐

6. Which if any state benefits do you receive? _____

7. How many children (if any) do you have? ☐☐

8. Who else (if anybody) do you live with? ☐

l=Live alone	4=With child/children under 18
2=With partner	5= With child/children over 18
3=With parents	6=Other (please specify) _____

9. Type of residence do you currently live? ☐☐

01=House/flat (owner occupied)	06=Sheltered housing
02=House/flat (Housing association)	07=Residential home
03=House/flat (private rent)	09=Hospital ward
04=Boarding out (incl. B+B)	10=No fixed abode
05=Hostel, supported/group home	

MANSA

Please estimate how satisfied are you with different aspects of your life that are listed below (accommodation, friendships, financial situation etc.) Use this scale below ranging from 1 to 7.

Satisfaction Scale

1	2	3	4	5	6	7
Couldn't be worse	Displeased	Mostly dissatisfied	Mixed	Mostly Satisfied	Pleased	Couldn't be better

mansa01	How satisfied are you with your life as a whole today?	
mansa02	How satisfied are you with your job (or training/education as your main occupation)? ***or if unemployed or retired*** How satisfied are you with being unemployed / retired?	
mansa03	How satisfied are you with your financial situation?	
mansa04	Do you have anyone who you would call a "close friend"?	0=NO 1=YES
mansa05	In the last week have you seen a friend? (visited a friend, been visited by a friend, or met a friend outside both your home and work)	0=NO 1=YES
mansa06	How satisfied are you with the number and quality of your friendships?	
mansa07	How satisfied are you with your leisure activities?	
mansa08	How satisfied are you with your accommodation?	
mansa09	In the past year have you been accused of a crime?	0=NO 1=YES
mansa10	In the past year have you been a victim of physical violence?	0=NO 1=YES
mansa11	How satisfied are you with your personal safety?	

mansa12	How satisfied are you with the people that you live with? ***or if you live alone*** How satisfied are you with living alone?	
mansa13	How satisfied are you with your sex life?	
mansa14	How satisfied are you with your relationship with your family	
mansa15	How satisfied are you with your physical health?	
mansa16	How satisfied are you with your mental health?	

Social Network Schedule - REVISED

WHO DID YOU SEE OR SPEAK TO (PHONE/EMAIL ETC) IN THE LAST WEEK? For each contact record how many times the participant saw/spoke to them.

Who you saw (ie Friend, Family member)		Number of contacts (#)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		

SIX

1. Employment

0 none
1 voluntary/ protected/ sheltered work
2 regular employment

2. Accommodation

0 homeless or 24hr supervised
1 sheltered or supported accommodation
2 independent accommodation

3. Partnership/Family

0 living alone
1 living with a partner or family

4. Friendship

0 not meeting a friend within the last week
1 meeting a friend within the last week

TIME USE SURVEY- LEISURE ACTIVITIES

I am now going to ask some questions about things that some people do in their spare time. For each activity that I mention could you please tell me whether of not you have done this in the last month, AND how often?

ACTIVITY	NUMBER OF TIMES	AMOUNT OF TIME
Been out to eat or drink at a café, restaurant, pub or wine bar		
Been to a shopping centre, or mall, apart from regular shopping for food and household items		
Been to some other place of entertainment (e.g. dance, club, bingo, casino)		
Been on any other outdoor trips (including going to places of natural beauty, picnics, going for a drive or going to the beach)		

How much time do you spend socialising? How many occasions in the last month have you seen friends, either visiting them or receiving visitors? How much time did you tend to spend socialising on each occasion on average?

Details:

Simpson Angus Scale

1. Gait: The patient is examined as he walks into the examining room, his gait, the swing of his arms, his general posture, all form the basis for an overall score for this item. This is rated as follows:

0= Normal
1= Diminution in swing while the patient is walking
2= Marked diminution in swing with obvious rigidity in the arm
3= Stiff gait with arms held rigidly before the abdomen
4= Stooped shuffling gait with propulsion and retropulsion

2. Arm Dropping: The patient and the examiner both raise their arms to shoulder height and let them fall to their sides. In a normal subject, a stout slap is heard as the arms hit the sides. In the patient with extreme Parkinson's syndrome, the arms fall very slowly:

0= Normal, free fall with loud slap and rebound
1= Fall slowed slightly with less audible contact and little rebound
2= Fall slowed, no rebound
3= Marked slowing, no slap at all
4= Arms fall as though against resistance; as though through glue

3. Shoulder Shaking: The subject's arms are bent at a right angle at the elbow and are taken one at a time by the examiner who grasps one hand and also clasps the other around the patient's elbow. The subject's upper arm is pushed to and fro and the humerus is externally rotated. The degree of resistance from normal to extreme rigidity is scored as follows:

0= Normal
1= Slight stiffness and resistance
2= Moderate stiffness and resistance
3= Marked rigidity with difficulty in passive movement
4= Extreme stiffness and rigidity with almost a frozen shoulder

4. Elbow Rigidity: The elbow joints are separately bent at right angles and passively extended and flexed, with the subject's biceps observed and simultaneously palpated. The resistance to this procedure is rated. (The presence of cogwheel rigidity is noted separately.)

0= Normal
1= Slight stiffness and resistance
2= Moderate stiffness and resistance
3= Marked rigidity with difficulty in passive movement
4= Extreme stiffness and rigidity with almost a frozen elbow

5. Wrist Rigidity or Fixation of Position: The wrist is held in one hand and the fingers held by the examiner's other hand, with the wrist moved to extension, flexion and ulnar and radial deviation:

0= Normal
1= Slight stiffness and resistance
2= Moderate stiffness and resistance
3= Marked rigidity with difficulty in passive movement
4= Extreme stiffness and rigidity with almost frozen wrist

6. Leg Pendulousness: The patient sits on a table with his legs hanging down and swinging free. The ankle is grasped by the examiner and raised until the knee is partially extended. It is then allowed to fall. The resistance to falling and the lack of swinging form the basis for the score on this item:

0= The legs swing freely
1= Slight diminution in the swing of the legs
2= Moderate resistance to swing
3= Marked resistance and damping of swing
4= Complete absence of swing

7. Head Dropping: The patient lies on a well-padded examining table and his head is raised by the examiner's hand. The hand is then withdrawn and the head allowed to drop. In the normal subject the head will fall upon the table. The movement is delayed in extrapyramidal system disorder, and in extreme parkinsonism it is absent. The neck muscles are rigid and the head does not reach the examining table. Scoring is as follows:

0= The head falls completely with a good thump as it hits the table
1= Slight slowing in fall, mainly noted by lack of slap as head meets the table
2= Moderate slowing in the fall quite noticeable to the eye
3= Head falls stiffly and slowly
4= Head does not reach the examining table

8. Glabella Tap: Subject is told to open eyes wide and not to blink. The glabella region is tapped at a steady, rapid speed. The number of times patient blinks in succession is noted:

0= 0-5 blinks
1= 6-10 blinks
2= 11-15 blinks
3= 16-20 blinks
4= 21 and more blinks

9. Tremor: Patient is observed walking into examining room and is then re-examined for this item:

0= Normal
1= Mild finger tremor, obvious to sight and touch
2= Tremor of hand or arm occurring spasmodically
3= Persistent tremor of one or more limbs
4= Whole body tremor

10. Salivation: Patient is observed while talking and then asked to open his mouth and elevate his tongue. The following ratings are given:

0= Normal
1= Excess salivation to the extent that pooling takes place
2= When excess salivation is present and might occasionally result in difficulty speaking
3= Speaking with difficulty because of excess salivation
4= Frank drooling

CALGARY Depression Scale

Interviewer: Ask the first question as written. Use follow up probes or qualifiers at your discretion. Time frame refers to last two weeks unless stipulated. N.B. The last item, #9, is based on observations of the entire interview.

1. DEPRESSION: How would you describe your mood over the last two weeks? Do you keep reasonably cheerful or have you been very depressed or low spirited recently? In the last two weeks how often have you (own words) every day? All day?

0. Absent	
1. Mild	Expresses some sadness or discouragement on questioning.
2. Moderate	Distinct depressed mood persisting up to half the time over last 2 weeks: present daily.
3. Severe	Markedly depressed mood persisting daily over half the time interfering with normal motor and social functioning.

2. HOPELESSNESS: How do you see the future for yourself? Can you see any future? - or has life seemed quite hopeless? Have you given up or does there still seem some reason for trying?

0. Absent	
1. Mild	Has at times felt hopeless over the last two weeks but still has some degree of hope for the future.
2. Moderate	Persistent, moderate sense of hopelessness over last week. Can be persuaded to acknowledge possibility of things being better.
3. Severe	Persisting and distressing sense of hopelessness.

3. SELF DEPRECIATION: What is your opinion of your self compared to other people? Do you feel better, not as good, or about the same as others? Do you feel inferior or even worthless?

0. Absent
1. Mild Some inferiority; not amounting to feeling of worthlessness.
2. Moderate Subject feels worthless, but less than 50% of the time.
3. Severe Subject feels worthless more than 50% of the time. May be challenged to acknowledge otherwise.

4. GUILTY IDEAS OF REFERENCE: Do you have the feeling that you are being blamed for something or even wrongly accused? What about? (Do not include justifiable blame or accusation. Exclude delusions of guilt.)

0. Absent
1. Mild Subject feels blamed but not accused less than 50% of the time.
2. Moderate Persisting sense of being blamed, and/or occasional sense of being accused.
3. Severe Persistent sense of being accused. When challenged, acknowledges that it is not so.

5. PATHOLOGICAL GUILT: Do you tend to blame yourself for little things you may have done in the past? Do you think that you deserve to be so concerned about this?

0. Absent
1. Mild Subject sometimes feels over guilty about some minor peccadillo, but less than 50% of time.
2. Moderate Subject usually (over 50% of time) feels guilty about past actions the significance of which he exaggerates.
3. Severe Subject usually feels s/he is to blame for everything that has gone wrong, even when not his/her fault.

6. MORNING DEPRESSION: When you have felt depressed over the last 2 weeks have you noticed the depression being worse at any particular time of day?

0. Absent No depression.
1. Mild Depression present but no diurnal variation.
2. Moderate Depression spontaneously mentioned to be worse in a.m.
3. Severe Depression markedly worse in a.m., with impaired functioning which improves in p.m.

7. EARLY WAKENING: Do you wake earlier in the morning than is normal for you? How many times a week does this happen?

0. Absent No early wakening.
1. Mild Occasionally wakes (up to twice weekly) 1 hour or more before normal time to wake or alarm time.
2. Moderate Often wakes early (up to 5 times weekly) 1 hour or more before normal time to wake or alarm.
3. Severe Daily wakes 1 hour or more before normal time.

8. SUICIDE: Have you felt that life wasn't worth living? Did you ever feel like ending it all? What did you think you might do? Did you actually try?

0. Absent
1. Mild Frequent thoughts of being better off dead, or occasional thoughts of suicide.
2. Moderate Deliberately considered suicide with a plan, but made no attempt.
3. Severe Suicidal attempt apparently designed to end in death (i.e.: accidental discovery or inefficient means).

9. OBSERVED DEPRESSION: Based on interviewer's observations during the entire interview. The question "Do you feel like crying?" used at appropriate points in the interview, may elicit information useful to this observation.

0. Absent
1. Mild Subject appears sad and mournful even during parts of the interview, involving affectively neutral discussion.
2. Moderate Subject appears sad and mournful throughout the interview, with gloomy monotonous voice and is tearful or close to tears at times.
3. Severe Subject chokes on distressing topics, frequently sighs deeply and cries openly, or is persistently in a state of frozen misery if examiner is sure that this is present.

CLIENT SERVICE RECEIPT INVENTORY (CSRI)

A. Community Health Care Services

At the baseline ask for the past 3 months. Otherwise, ask for past month.

Healthcare provider		(circle)	*Number of contacts*	*Average duration per contact* **1 0-5 minutes** **2 6-15 minutes** **3 16-30 minutes** **4 31-45 minutes** ***5 46-60 minutes*** **6 over 60 minutes**
csriAa	A General practitioner	csriAa1 No Yes	csriAa2	csriAa3
csriAb	B Primary care nurse	csriAb1 No Yes	csriAb2	csriAb3
csriAc	C. Social worker	csriAc1 No Yes	csriAc2	csriAc3
csriAd	D Counsellor	csriAd1 No Yes	csriAd2	csriAd3
csriAe	Aeother E Other: _____	csriAe1 No Yes	csriAe2	csriAe3

B.Specialized Services *Speciality*		*In-patient stay*	*Number of nights in hospital*	*Hospital out-patient contact*	*Number of out-patient contacts*	*Out-patient contacts out of hospital*	*Number of out-patient contacts out of hospital*
csriBa	Psychiatry	csriBa1 No Yes	csriBa2	csriBa3 day hosp No Yes	csriBa4 days in day hosp	csriBa5 No Yes	csriBa6
csriBb	Psychologist	[redacted]	[redacted]	csriBb3 No Yes	csriBb4	csriBb5 No Yes	csriBb6
csriBc	Other psychotherapist (not psychiatrist or psychologist)	[redacted]	[redacted]	csriBc3 No Yes	csriBc4	csriBc5 No Yes	csriBc6
csriBd	Cardiology	csriBd1 No Yes	csriBd2	csriBd3 No Yes	csriBd4	csriBd5 No Yes	csriBd6
csriBe	Neurology	csriBe1 No Yes	csriBe2	csriBe3 No Yes	csriBe4	csriBe5 No Yes	csriBe6
csriBf	Dermatology	csriBf1 No Yes	csriBf2	csriBf3 No Yes	csriBf4	csriBf5 No Yes	csriBf6
csriBg	Internal medicine/Internist	csriBg1 No Yes	csriBg2	csriBg3 No Yes	csriBg4	csriBg5 No Yes	csriBg6
csriBh	Gastroenterology	csriBh1 No Yes	csriBh2	CsriBh3 No Yes	csriBh4	csriBh5 No Yes	csriBh6
csriBi	Radiology	csriBi1 No Yes	csriBi2	csriBi3 No Yes	csriBi4	csriBi5 No Yes	csriBi6
csriBj	Otorhinolaryngologist Ear, nose, throat specialist	csriBj1 No Yes	csriBj2	csriBj3 No Yes	csriBj4	csriBj5 No Yes	csriBj6
csriBk	Surgery	csriBk1 No Yes	csriBk2	csriBk3 No Yes	csriBk4	criBk5 No Yes	csriBk6
csriBl	Haematology	csriBl1 No Yes	csriBl2	csriBl3 No Yes	csriBl4	csriBl5 No Yes	csriBl6
csriBm	Endocrinology	csriBm1 No Yes	csriBm2	csriBm3 No Yes	csriBm4	csriBm5 No Yes	csriBm6
csriBn	Gynaecologist	csriBn1 No Yes	csriBn2	csriBn3 No Yes	csriBn4	csriBn5 No Yes	csriBn6
csriBo	Urology	csriBo1 No Yes	csriBo2	csriBo3 No Yes	csriBo4	csriBo5 No Yes	csriBo6

C. Medication

csriBp	Dentist	csriBp1 No Yes	csriBp2	csriBp3 No Yes	csriBp4	csriBp5 No Yes	csriBp6
csriBr	Eye specialist/oculist	csriBr1 No Yes	csriBr2	csriBr3 No Yes	csriBr4	csriBr5 No Yes	csriBr6
csriBs	Other (please specify) Bsother_____	csriBs1 No Yes	csriBs2	csriBs3 No Yes	csriBs4	csriBs5 No Yes	csriBs6

csriC	C1. In the last 12 months (baseline)/ in the last 2 months (follow-ups) have you been taking medication for any health problems?			0=No 1=Yes
	If yes: what are the names of the drugs you take (if known), dosage (if known) and what do you take them for? (NB. Include both mental and physical health medication)			
		Name:	**Dose (mg/day):**	**What is it for:**
csriCa	Drug 1:	CsriCa1	csriCa2.	csriCa3
csriCb	Drug 2:	csriCb1	csriCb2	csriCb3
csriCc	Drug 3:	csriCc1	csriCc2	csriCc3
csriCd	Drug 4:	csriCd1	csriCd2	csriCd3
csriCe	Drug 5:	csriCe1	csriCe2	csriCe3
csriCf	Drug 6:	csriCf1	csriCf2	csriCf3
(If you take more than 6 drugs, please record the details on the back of this form)				

E. Your Employment

csriE1	**If participant currently employed, ask:**: How many days off work over the last 12 months (baseline)/ in the last 2 months (follow-ups) because of health reasons?	

EQ-5D-5L: Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

MECCA - The Client Satisfaction Questionnaire

Please help us to improve our service by answering some questions about the services you have received. We are interested in your honest opinions, whether they are positive or negative. *Please answer all of the questions.* We also welcome your comments and suggestions. Thank you very much, we appreciate your help.

CIRCLE YOUR ANSWER:

1. How would you rate the quality of the service you have received?

4	3	2	1
Excellent	Good	Fair	Poor

2. Did you get the kind of service you wanted?

1	2	3	4
No Definitely not	No, Not really	Yes, generally	Yes, definitely

3. To what extent has this service met your needs?

4	3	2	1
Almost all of my needs have been met	Most of my needs have been met	Only a few of my needs have been met	None of my needs have been met

4. If a friend were in need of similar help, would you recommend this service to him/her?

1	2	3	4
No, definitely not	No, I don't think so	Yes, I think so	Yes, definitely

5. How satisfied are you with the amount of help you have received?

1	2	3	4
Quite dissatisfied	Indifferent or mildly dissatisfied	Most satisfied	Very satisfied

6. Have the services you have received helped you to deal more effectively with your problems?

4	3	2	1
Yes, they helped a great deal	Yes, they helped somewhat	No, they really didn't help	No, they seemed to make things worse

7. Overall, how satisfied are you with the service you have received?

4	3	2	1
Very satisfied	Mostly satisfied	Indifferent or mildly dissatisfied	Quite dissatisfied

8. If you were to seek help again, would you come back to this service?

1	2	3	4
No, definitely not	No, I don't think so	Yes, I think so	Yes definitely

EME
HS&DR
HTA
PGfAR
PHR

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